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SCIENTIFIC OPINION

Scientific Opinion on the public health hazards to be covered by inspection of meat (bovine animals)[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2,3]

With the contribution of the EFSA Panels on Contaminants in the Food Chain (CONTAM) and Animal Health and Welfare (AHAW)

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A risk ranking process identified *Salmonella* spp. and pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) as current high-priority biological hazards for meat inspection of bovine animals. As these hazards are not detected by traditional meat inspection, a meat safety assurance system for the farm-to-chilled carcass continuum using a risk-based approach was proposed. Key elements of the system are risk-categorisation of slaughter animals for high-priority biological hazards based on improved food chain information, as well as risk-categorisation of slaughterhouses according to their capability to control those hazards. Omission of palpation and incision during *post-mortem* inspection for animals subjected to routine slaughter may decrease spreading and cross-contamination with the high-priority biological hazards. For chemical hazards, dioxins and dioxin-like polychlorinated biphenyls were ranked as being of high potential concern; all other substances were

[1] On request from the European Commission, Question No EFSA-Q-2011-00364, EFSA-Q-2011-00111 and EFSA-Q-2011-00324, adopted on 6 June 2013.

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[3] Acknowledgement: The Panel wish to thank the members of the BIOHAZ Working Group on public health hazards to be covered by inspection of meat (bovines): Declan Bolton, Sava Buncic, John D Collins (deceased), Pierre Dorny, Arie Havelaar, Truls Nesbakken, John Sofos and the hearing expert Radu Blaga; and the CONTAM Panel: Diane Benford, Sandra Ceccatelli, Bruce Cottrill, Michael DiNovi, Eugenia Dogliotti, Lutz Edler, Peter Farmer, Peter Fürst, Laurentius (Ron) Hoogenboom, Helle Katrine Knutsen, Anne-Katrine Lundebye Haldorsen, Manfred Metzler, Carlo Stefano Nebbia, Michael O'Keeffe, Ivonne Rietjens, Dieter Schrenk, Vittorio Silano, Hendrik van Loveren, Christiane Vleminckx, and Pieter Wester; and the CONTAM Working Group on meat inspection and contaminants: Bert-Jan Baars, Johanna Fink-Gremmels, Reinhard Fries, Peter Fürst, Steven McOrist, Carlo Nebbia and Michael O'Keeffe; and the AHAW Panel: Edith Authie, Charlotte Berg, Anette Bøtner, Howard Browman, Ilaria Capua, Aline De Koeijer, Klaus Depner, Mariano Domingo, Sandra Edwards, Christine Fourichon, Frank Koenen, Simon More, Mohan Raj, Liisa Sihvonen, Hans Spoolder, Jan Arend Stegeman, Hans-Hermann Thulke, Ivar Vågsholm, Antonio Velarde, Preben Willeberg and Stéphan Zientara; and the AHAW Working Group on meat inspection and animal health and welfare: Donald Broom, Marcus Doherr, Mariano Domingo, Javier Dominguez, Frank Koenen, Simon More, Declan Murray, Pascal Oltenacu, Mohan Raj, Mo Salman, Moez Sanaa, Martin Wierup and Preben Willeberg for the preparatory work on this scientific opinion; and ECDC (European Centre for Disease Prevention and Control) staff: Eva Warns-Petit and Vicente Lopez Chavarrias; and the EFSA staff Luis Vivas-Alegre, Ernesto Liébana, Elena Mazzolini, Marios Georgiadis (BIOHAZ), Silvia Inés Nicolau-Solano, Valeriu Curtui, Gina Cioacata (CONTAM), Karen Mackay, Gabriele Zancanaro, Milen Georgiev, Ana Afonso (AHAW) for the support provided to this scientific opinion.

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ranked as of medium or lower concern. Monitoring programmes for chemical hazards should be more flexible and based on the risk of occurrence, taking into account the completeness and quality of the food chain information supplied and the ranking of chemical substances, which should be regularly updated to include new hazards. Control programmes across the food chain, national residue control programmes, feed control and monitoring of environmental contaminants should be better integrated. Meat inspection is a valuable tool for surveillance and monitoring of animal health and welfare conditions. Omission of palpation and incision would reduce detection effectiveness for bovine tuberculosis and would have a negative impact on the overall surveillance system especially in officially tuberculosis free countries. The detection effectiveness for bovine cysticercosis, already low with the current meat inspection system, would result in a further decrease, if palpation and incision are removed. Extended use of food chain information could compensate for some, but not all, the information on animal health and welfare lost if only visual *post-mortem* inspection is applied.

KEY WORDS

meat inspection, bovine animal, cattle, contaminants, residues, surveillance, slaughterhouse

SUMMARY

Following a request from the European Commission, the EFSA Panel on Biological Hazards (BIOHAZ) was asked to deliver a Scientific Opinion on the public health hazards to be covered by inspection of meat from several animal species, with the contribution of the Panel on Contaminants in the Food Chain (CONTAM) and the Panel on Animal Health and Welfare (AHAW). Briefly, the main risks to public health that should be addressed by the meat inspection system were identified and ranked; the strengths and weaknesses of the current meat inspection system were evaluated; recommendations were made for inspection methods addressing hazards not covered by the current meat inspection system; and recommendations for adaptations of inspection methods and/or frequencies of inspection that provide an equivalent level of protection were made. In addition, the implications for animal health and animal welfare of any proposed changes to current inspection methods were assessed. This opinion covers the inspection of meat from bovine animals.

The Terms of Reference from the European Commission requested two opinions, one covering bovine animals under six weeks old and the other covering bovine animals over six weeks old. It was determined that within a true risk-based meat inspection concept, it is not necessary to design and apply a separate meat inspection system for individual bovine species or farming systems or animal age categories. Rather, a universal meat inspection framework can be designed and applied that would allow risk categorisation of animals based on individual farm-related food chain information (FCI), which also includes farming system and animal age category components. Furthermore, the available data from the National Residue Control Programmes (NRCPs) do not readily discriminate between the two age groups. Therefore, the assessment did not differentiate between these two age groups in terms of biological hazards, chemical residues and contaminants, and subsequently a single opinion is provided.

Decision trees were developed and used for priority ranking of biological and chemical hazards relevant to meat inspection. Biological hazards introduced and/or for which the risk for public health requires bacterial growth during steps following carcass chilling (*Listeria monocytogenes*, and toxins of *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus aureus*) were excluded at the first step of the ranking and not considered further. The priority ranking of biological hazards was based on the assessment of: (i) the magnitude of the human health impact based on reported incidence, (ii) the severity of the disease in humans based on fatalities among reported cases, and (iii) the strength of evidence that meat from bovine animals is an important risk factor for the disease in humans. Risk ranking of chemical hazards into categories of potential concern was based on the outcomes of the NRCPs, as defined in Council Directive 96/23/EC for the period 2005–2010, and of other testing programmes, as well as on substance-specific parameters such as the toxicological profile and the likelihood of the occurrence of residues and contaminants in bovine animals.

Based on the limited data available and expert opinion employed for the ranking, biological hazards categorised as low-priority for bovine meat inspection were *Bacillus anthracis*, *Campylobacter* spp. (thermophilic), *Sarcocystis hominis* and *Taenia saginata*. These hazards were not considered further because it was determined that the low-priority ranking was not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures). However, the effect of carcass chilling on reduced survival of *Campylobacter* spp. (thermophilic) on carcasses of bovine animals as a non-hazard-specific control measure has to be taken into account. Bovine meat-borne biological hazards categorised as of high-priority for meat inspection were *Salmonella* spp. and pathogenic verotoxigenic *Escherichia coli* (pathogenic VTEC). *Toxoplasma gondii* and extended spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene carrying *E. coli* were characterised as of 'undetermined' priority for bovine meat inspection because the data available were insufficient for conclusive ranking. It should be noted that the ranking of biological hazards into specific categories is based on current knowledge and available data, and therefore ranking should be updated regularly when new information and data become available and including 'new hazards'.

For chemical hazards, dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern due to their known bioaccumulation in the food chain, the risk of exceedance of maximum levels (MLs) and in consideration of their toxicological profile; all other substances were ranked as of medium or lower concern. It should be noted that the ranking into specific risk categories of chemical hazards is based on current knowledge and available data and therefore ranking should be updated regularly, taking account of new information and data and including 'new hazards'.

The main elements of the current bovine meat inspection system include analysis of FCI, *ante-mortem* examination of animals and *post-mortem* examination of carcasses and organs. The assessment of the strengths and weaknesses of the current meat inspection was primarily based on its contribution to the control of the identified bovine meat-borne human health hazards.

With regard to biological hazards, strengths identified for the current meat inspection system were that, in principle, adequate collection and proper utilisation of FCI can be useful and beneficial in *ante-* and/or *post-mortem* bovine meat inspection. FCI, used as part of *ante-mortem* inspection, provides information related to veterinary treatments and disease history during animal rearing and helps focus *ante-mortem* and/or *post-mortem* meat inspection on animal and public health concerns. *Ante-mortem* and *post-mortem* inspection of bovine animals and carcasses enable detection of visible abnormalities, providing important benefits in monitoring animal health and welfare. *Ante-mortem* inspection of bovine animals enables animal identification for traceability, and can be used to verify FCI given by the farmer and to provide feedback to producers on problems detected, but usually for issues not related to public health. *Ante-mortem* visual examination detects bovine animals with diarrhoea as well as visible faecal contamination that may be associated with increased risk of microbial cross-contamination during slaughter. *Post-mortem* inspection detects visual faecal contamination on dressed bovine carcasses that may indicate potential exposure to the identified high-priority bovine meat-borne hazards. With regard to chemical hazards, it was noted that current procedures for sampling and testing are, in general, well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples. In addition, the identification system for bovine animals provides full transparency of the European Union (EU) bovine stock and the current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring. The regular sampling and testing for chemical residues and contaminants is an important disincentive to the development of undesirable practices and the prescriptive sampling system allows for equivalence in the control of EU veal/beef.

A number of weaknesses were also identified for the existing bovine meat inspection system. With regard to biological hazards, currently, FCI collection is not harmonised, is used only to a limited extent, and is not adequate to allow classification of bovine farms/herds in relation to potential presence of the identified high-priority bovine meat-borne biological hazards *Salmonella* spp. and pathogenic VTEC. Current *ante-mortem* and *post-mortem* macroscopic inspection are not able to detect any of the identified high-priority bovine meat-borne biological hazards. Judgement of the fitness of bovine meat for human consumption by current *post-mortem* inspection does not differentiate food safety aspects from meat quality aspects, prevention of animal diseases, and occupational hazards. Manual handling of meat, including use of palpation/incision techniques, during *post-mortem* inspection does not contribute to the detection of the identified high-priority bovine meat-borne hazards; in fact, it may increase and spread these hazards by cross-contamination.

In the case of chemical hazards, a major weakness is that, with very few exceptions, the presence of chemical hazards cannot be identified by current inspection procedures at the slaughterhouse level, and there is a lack of sufficient cost-effective and reliable screening methods. In addition, sampling is mostly prescriptive rather than risk or information based. There is limited ongoing adaptation of the sampling and testing programmes to the results of the residue monitoring programmes, with poor integration between the testing of feed materials for undesirable substances and the NRCPs. In

addition, sampling under the NRCPs reflects only a part of testing done by a number of MSs, the results of which should be taken into consideration.

Since none of the bovine meat-borne biological hazards categorised as of high-priority can be detected by traditional macroscopic meat inspection, other approaches are necessary to control these hazards. This can be best achieved using FCI and risk-based controls along the farm to chilled bovine carcass continuum. Consequently, an integrated bovine meat safety assurance system has been outlined and includes the need for clear and measurable high-priority meat-borne hazard-based EU targets (hazard prevalence and/or concentration) to be achieved by Food Business Operators (FBOs) in/on bovine carcasses and, when appropriate, in bovine farms/herds. Risk-based targets derived from harmonised monitoring are not yet available for the bovine meat-bone biological hazards categorised as of high-priority for meat inspection (i.e. *Salmonella* spp. and pathogenic VTEC).

An important element of an integrated bovine meat safety assurance system should be risk categorisation of farms/herds of bovine animals based on farm descriptors and historical data as well as herd-specific information, including monitoring of Harmonised Epidemiological Indicators (HEI) as described in the related Scientific Report of EFSA on Technical specifications on HEI to be covered by meat inspection of bovine animals. Significant differences exist among bovine farms/herds in farming practices, risk factors and controls used in respect to *Salmonella* spp. and pathogenic VTEC, and thus potentially in the corresponding status of bovine animal batches sent to slaughter. This indicates that it should be possible to risk categorise bovine animal batches sent to slaughter for *Salmonella* spp. and pathogenic VTEC through use of FCI, based on farm/herd historical data, and information gathered through application of appropriate HEI.

Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments (PAH) and from Hazard Analysis Critical Control Point (HACCP) programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance. High-risk animal batches or herds should be subjected to additional slaughter hygiene control measures and possibly complemented with decontamination treatments, or might be directed to slaughterhouses having demonstrated an enhanced ability to control carcass contamination. Where necessary, meat derived from carcasses of high risk animals may be used only for heat processed or cooked products. Animal batches of unknown risk category for a given hazard or mixed batches that include animals of unknown or high risk category for a given hazard should be handled as of high risk.

Regarding potential adaptations of current meat inspection procedures, FCI can be improved by including information on participation in quality assurance schemes and by improved feedback to the primary producer, as this would likely result in the production of healthier animals. *Ante-mortem* inspection assesses the general health status of animals and helps in the detection of animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current visual inspection methods do not increase the microbiological risk to public health, no adaptations for the existing visual *ante-mortem* inspection are required or recommended. Visual *post-mortem* inspection of bovine carcasses can detect faecal contamination that may indicate potential exposure to the identified high-priority hazards. However, palpation/incision, as used in current *post-mortem* inspection, should be omitted in the case of bovine animals subjected to routine slaughter, because these procedures do not add to the identification and control of the high-priority bovine meat-borne hazards and may increase their spreading and cross-contamination.

Manual techniques of examination should be limited to suspect bovine animals and should be performed, where appropriate, separately from the slaughterline operation. Abnormalities on aesthetic/meat quality grounds can be eliminated through an adequate meat quality assurance system, which may also detect abnormalities associated with non-meat-borne and low-priority hazards, as well as related data recording and distribution.

A series of recommendations are made in relation to biological hazards, mainly on data needs for future hazard identification and risk or priority ranking exercises and on the need for ways to risk categorise bovine farms/herds and to carry out PHA of slaughterhouses through the use of indicator organisms.

The types and likelihood of occurrence of chemical residues and contaminants in bovine animals vary due to the diversity of bovine farming in the EU. It is recommended that future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and the ranking of chemical substances into categories of potential concern, which ranking needs to be regularly updated. Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, and should also include 'new hazards'. 'New' chemical hazards identified are largely persistent organic pollutants that have not been comprehensively covered by the sampling plans of the current meat inspection or which have not been included in such sampling plans; sampling and testing plans should be developed for these chemical hazards. There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants. A series of further recommendations, dealing with control measures, testing and analytical techniques, are made in relation to chemical hazards.

The implications for surveillance of animal health and welfare of the changes proposed to the current meat inspection system were evaluated quantitatively and qualitatively. The proposed changes related to biological hazards included shorter transport and lairage time, focusing and expanding FCI, omission of palpation and incision in animals subjected to routine slaughter at *post-mortem* inspection and additional control measures of high-risk herds. Recommendations on chemical hazards included the ranking system for chemical substances and its updating, development of risk-based strategies for sampling, including 'new hazards' identified, and improvement of analytical techniques.

The quantitative analysis showed that the difference in detection fraction between current meat inspection and a visual only procedure was significant for granuloma/bovine tuberculosis and *Taenia saginata* cysticercosis. A significant reduction in the probability of detection at meat inspection of respiratory diseases, cysticercosis, fasciolosis (primarily for mild cases) and bovine tuberculosis was also noted. There was little difference in component sensitivity between the current and the visual-only meat inspection for any of the exotic diseases considered. Animal welfare conditions were not affected by the change to visual-only inspection, as most of the conditions can be detected during effective *ante-mortem* inspection.

Following the qualitative analysis, it was concluded that a negative impact on bovine tuberculosis detection would occur if palpation and incision of relevant organs (lung, respiratory tract lymph nodes) were removed from inspection tasks. In order not to decrease the overall sensitivity of surveillance, the experts concluded that these inspection tasks should be retained in the meat inspection system. Additional modelling performed for bovine tuberculosis showed that a reduction of the sensitivity of the detection test at individual (animal) level would have a negative impact on the overall surveillance system sensitivity, especially in the Officially Tuberculosis Free (OTF) countries, where meat inspection is the only surveillance system in place.

The sensitivity of the current meat inspection system for detection of bovine cysticercosis is considered to be low, and a further significant decrease in effectiveness of detection would be expected in moving from the current to a visual only system. The experts concluded that if a visual only meat inspection system were to be adopted, alternative procedures should then be applied that provide equivalent or even increased capability of detection than, that of current meat inspection. For fasciolosis and respiratory diseases, it was concluded by the experts that the risk to animal health/welfare caused by a change to a visual only meat inspection method is probably low.

Animal based welfare indicators have been developed for the on-farm assessment of welfare, and specifically of lameness in bovine animals (dairy cows), and they could be adapted for use during routine *ante-mortem* inspection in slaughterhouses. FCI should include animal welfare status in order to complement the slaughterhouse surveillance systems (*ante-mortem* and *post-mortem* inspection) and the latter could be used to identify on-farm welfare status.

Other recommendations on biological and chemical hazards would not have a negative impact on surveillance of animal diseases and welfare conditions.

DEDICATION

The BIOHAZ Panel and the BIOHAZ Unit wish to dedicate this Scientific Opinion to the memory of Prof. John D. Collins, distinguished former chair of the BIOHAZ Panel and member of this working group.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 854/2004 of the European Parliament and of the Council lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Inspection tasks within this Regulation include:

- Checks and analysis of food chain information
- *Ante-mortem* inspection
- Animal welfare
- *Post-mortem* inspection
- Specified risk material and other by-products
- Laboratory testing

The scope of the inspection includes monitoring of zoonotic infections and the detection or confirmation of certain animal diseases without necessarily having consequences for the placing on the market of meat. The purpose of the inspection is to assess if the meat is fit for human consumption in general and to address a number of specific hazards: in particular the following issues: transmissible spongiform encephalopathies (only ruminants), cysticercosis, trichinosis, glanders (only solipeds), tuberculosis, brucellosis, contaminants (e.g. heavy metals), residues of veterinary drugs and unauthorised substances or products.

During their meeting on 6 November 2008, Chief Veterinary Officers (CVO) of the Member States agreed on conclusions on modernisation of sanitary inspection in slaughterhouses based on the recommendations issued during a seminar organised by the French Presidency from 7 to 11 July 2008. The CVO conclusions have been considered in the Commission Report on the experience gained from the application of the Hygiene Regulations, adopted on 28 July 2009. Council Conclusions on the Commission report were adopted on 20 November 2009 inviting the Commission to prepare concrete proposals allowing the effective implementation of modernised sanitary inspection in slaughterhouses while making full use of the principle of the 'risk-based approach'.

In accordance with Article 20 of Regulation (EC) No 854/2004, the Commission shall consult EFSA on certain matters falling within the scope of the Regulation whenever necessary.

EFSA and the Commission's former Scientific Committee on Veterinary Measures relating to Public Health have issued in the past a number of opinions on meat inspection considering specific hazards or production systems separately. In order to guarantee a more risk-based approach, an assessment of the risk caused by specific hazards is needed, taking into account the evolving epidemiological situation in Member States. In addition, methodologies may need to be reviewed taking into account risks of possible cross-contamination, trends in slaughter techniques and possible new inspection methods

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The scope of this mandate is to evaluate meat inspection in order to assess the fitness of the meat for human consumption and to monitor food-borne zoonotic infections (public health) without jeopardising the detection of certain animal diseases nor the verification of compliance with rules on animal welfare at slaughter. If and when the current methodology for this purpose would be considered not to be the most satisfactory to monitor major hazards for public health, additional methods should be recommended as explained in detail under points 2 and 4 of the terms of reference. The objectives of the current legal provisions aimed at carrying out meat inspection on a risk-based analysis should be maintained.

In order to ensure a risk-based approach, EFSA is requested to provide scientific opinions on meat inspection in slaughterhouses and, if considered appropriate, at any other stages of the production chain, taking into account implications for animal health and animal welfare in its risk analysis. In addition, relevant international guidance should be considered, such as the Codex Code of Hygienic Practice for Meat (CAC/RCP 58–2005), and Chapter 6.2 on Control of biological hazards of animal health and public health importance through *ante-* and *post-mortem* meat inspection, as well as Chapter 7.5 on slaughter of animals of the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE).

The following species or groups of species should be considered, taking into account the following order of priority identified in consultation with the Member States: domestic swine, poultry, bovine animals over six weeks old, bovine animals under six weeks old, domestic sheep and goats, farmed game and domestic solipeds.

In particular, EFSA, in consultation with the European Centre for Disease Prevention and Control (ECDC), is requested within the scope described above to:

1. Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e .g. breeding compared to fattening animals).

2. Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

3. If new hazards currently not covered by the meat inspection system (e.g. *Salmonella*, *Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

4. Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see annex 2 of the mandate). When appropriate, food chain information should be taken into account.

APPROACH TAKEN TO ANSWER THE TERMS OF REFERENCE

1. Scope

The scope of the mandate is to evaluate meat inspection in a public health context, while animal health and welfare issues are to be covered relative to possible implications on them by adaptations/alterations to current inspection methods, or by introduction of novel inspection methods proposed by Opinion.

Issues other than those of public health significance but that still may compromise fitness of the meat for human consumption (Regulation (EC) No 854/2004, Annex I, Section II, Chapter V) are outside the scope of the mandate; an example of this is the quality issue of dark firm and dry (DFD) meat. Transmissible spongiform encephalopathies (TSEs) are also outside the scope of the mandate.

The impact of changes to meat inspection procedures on the occupational health of slaughterhouse workers, inspectors, etc is also outside the scope of the mandate. Additionally, hazards representing primarily occupational health risk, controls related to any hazard at any meat chain stage beyond the slaughterhouse, and the implications for environmental protection, are not dealt with in this document.

2. Approach

In line with Article 20 of Regulation (EC) No 854/20044 the European Commission has recently submitted a mandate to EFSA (M-20100232) to cover different aspects of meat inspection. The mandate comprises two requests: one for Scientific Opinions and one for Technical Assistance.

The European Food Safety Authority (EFSA) has been requested to issue Scientific Opinions related to inspection of meat from different species. In addition, EFSA has been asked to provide technical assistance on harmonised epidemiological criteria for specific hazards for public health that can be used by risk managers to consider adaptation of meat inspection methodology.

Meat inspection is defined by Regulation 854/2004. The species or groups of species to be considered are: domestic swine, poultry, bovine animals over six weeks old, bovine animals under six weeks old, domestic sheep and goats, farmed game and domestic solipeds.

Taking into account the complexity of the subject and the fact that consideration has to be given to zoonotic hazards, animal health and welfare issues, and to chemical hazards (e.g. residues of veterinary drugs and chemical contaminants), the involvement of several EFSA units was necessary. More specifically, the delivery of the Scientific Opinion was allocated to the Biological Hazards (BIOHAZ) and Animal Health and Welfare (AHAW) and Contaminants in the Food Chain (CONTAM) Panels and the delivery of technical assistance was allocated to the Biological Monitoring (BIOMO), Scientific Assessment Support (SAS) and Dietary & Chemical Monitoring (DCM) Units.

This Scientific Opinion therefore concerns the assessment of meat inspection in bovine animals, and it includes the answer to the terms of reference proposed by the European Commission. Owing to the complexity of the mandate, the presentation of the outcome does not follow the usual layout. For ease of reading, the main outputs from the three scientific panels (BIOHAZ, CONTAM and AHAW) are presented at the beginning of the document. The scientific justifications of these outputs are found in the various Appendices as adopted by these panels, namely Biological Hazards (Appendix A), Chemical Hazards (Appendix B) and the potential impact that the proposed changes envisaged by these two could have on Animal Health and Welfare (Appendix C).

CONCLUSIONS AND RECOMMENDATIONS ANSWERING THE TERMS OF REFERENCE

CONCLUSIONS

TOR 1. ***Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e .g. breeding compared to fattening animals).***

Conclusions on biological hazards

- A decision tree was developed and used for priority ranking bovine animal meat-borne biological hazards. Hazards that are introduced and/or for which the risk for public health requires bacterial growth during processing steps after carcass chilling (*Listeria monocytogenes*, and toxins of *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus aureus*) were excluded at the first stage of the ranking and not considered further.

- Based on the limited data available and expert opinion, biological hazards categorised as low-priority for bovine meat inspection were *Bacillus anthracis*, *Campylobacter* spp. (thermophilic), *Sarcocystis hominis* and *Taenia saginata*. These hazards were not considered further because it was determined that their low-priority ranking was not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures).However, the effect of carcass chilling on reduced survival of *Campylobacter* spp. (thermophilic) on carcasses of bovine animals as a non-hazard-specific control measure has to be taken into account.

- The bovine meat-bone biological hazards categorised as of high-priority for meat inspection were *Salmonella* spp. and pathogenic verotoxigenic *Escherichia coli* (pathogenic VTEC).

- *Toxoplasma gondii* and extended spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene carrying *E. coli* were carachterised as of 'undetermined' priority for bovine meat inspection because available data were insufficient for conclusive ranking.

Conclusions on chemical hazards

- A multi-step approach was used for the identification and ranking of chemical hazards. Evaluation of the 2005–2010 national residue control plans (NRCPs) outcome for bovine animals indicated that only 0.25 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. Potentially higher exposure of consumers to these substances from bovine meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedure. Available data, however, do not allow for a reliable assessment of consumer exposure.

- Ranking of chemical residues and contaminants in bovine animals based on predefined criteria, relating to bioaccumulation, toxicological profile and likelihood of occurrence, and taking into account the findings from the NRCPs for the period 2005–2010 was as follows:

  - Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern due to their known bioaccumulation in the food chain, the risk of exceedance of maximum levels (MLs) and in consideration of their toxicological profile.

- Stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones and beta-agonists, especially clenbuterol, were ranked as being of medium potential concern because of their toxicity to humans, their efficacy as growth promoters in cattle and the incidence of non-compliant results.

- Chloramphenicol and nitrofurans were ranked as being of medium potential concern, as they have proven toxicity to humans, are effective as antibacterial treatments for cattle and residues in bovine carcasses have been found from the NRCPs in various Member States (MSs).

- Non dioxin-like polychlorinated biphenyls (NDL-PCBs) bioaccumulate and there is a risk for exceedance of the MLs, but they were ranked in the category of medium potential concern because they are less toxic than dioxins and DL-PCBs.

- The chemical elements cadmium, lead and mercury were allocated to the medium potential concern category, taking into account the number of non-compliant results reported under the NRCPs and their toxicological profile.

- Residues originating from other substances listed in Council Directive 96/23/EC were ranked as of low or negligible potential concern due to the toxicological profile of these substances at residue levels in edible tissues, or to the very low or non occurrence of non-compliant results in the NRCPs 2005–2010 and/or to the natural occurrence in bovine animals of some of these substances.

TOR 2. ***Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at ante-mortem or post-mortem inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.***

Conclusions on biological hazards

The assessment of the strengths and weaknesses of the current meat inspection was primarily focused on its contribution to the control of the identified high-priority bovine meat-borne human health hazards.

- Strengths of the current meat inspection methodology for the high-priority biological hazards are as follows:

  - In principle, adequate collection and proper utilisation of Food Chain Information (FCI) can be useful and beneficial in *ante-* and/or *post-mortem* bovine meat inspection. FCI, used as part of *ante-mortem* inspection, provides information related to veterinary treatments and disease history during animal rearing and helps focus *ante-mortem* and/or *post-mortem* meat inspection on animal and public health concerns.

  - *Ante-mortem* and *post-mortem* inspection of bovine animals and carcasses enable detection of visible abnormalities, providing important benefits in monitoring animal health and welfare.

  - *Ante-mortem* inspection of bovine animals enables animal identification for traceability, and can be used to verify FCI given by the farmer and to provide feedback to producers on problems detected, but usually for issues not related to public health. *Ante-mortem* visual examination detects bovine animals with diarrhoea as well as visible faecal contamination

that may be associated with increased risk of microbial cross-contamination during slaughter.

- *Post-mortem* inspection detects visual faecal contamination on dressed bovine carcasses that may indicate potential exposure to the identified high-priority bovine meat-borne hazards.

- Weaknesses of the current meat inspection methodology for high-priority biological hazards are as follows:

  - Currently, FCI collection is not harmonised, is used only to a limited extent, and is not adequate to allow classification of bovine farms/herds in relation to potential presence of the identified high-priority bovine meat-borne biological hazards *Salmonella* spp. and pathogenic VTEC.

  - Current *ante-mortem* and *post-mortem* macroscopic inspection are not able to detect any of the identified high-priority bovine meat-borne biological hazards.

  - Judgement of the fitness of bovine meat for human consumption by current *post-mortem* inspection does not differentiate food safety aspects from meat quality aspects, prevention of animal diseases, and occupational hazards.

  - Manual handling of meat, including use of palpation/incision techniques, during *post-mortem* inspection does not contribute to the detection of the identified high-priority bovine meat-borne hazards; in fact, it may increase and spread these hazards by cross-contamination.

Conclusions on chemical hazards

- The strengths of the current meat inspection methodology for chemical hazards are as follows:

  - The current procedures for sampling and testing are a mature system that is, in general, well established and coordinated including follow-up actions subsequent to the identification of non-compliant samples. In addition, the identification system for bovine animals provides full transparency of the EU bovine stock.

  - The regular sampling and testing for chemical residues and contaminants in the system is an important disincentive to the development of undesirable practices.

  - The prescriptive sampling system allows for equivalence in the control of EU veal/beef. Any forthcoming measures have to ensure that the control of imports from Third Countries remains equivalent to the controls within the domestic market.

  - The current combination of animal traceability, ante-mortem inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring.

- The weaknesses of the current meat inspection methodology for chemical hazards are as follows:

  - With very few exceptions, the presence of chemical hazards cannot be identified by current ante-/post-mortem meat inspection procedures at the slaughterhouse level, indicating the need for further harmonisation of risk reduction strategies along the entire food chain.

- At present, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs in terms of communication and follow-up testing strategies or interventions.

- Under the current system, sampling is mostly prescriptive rather than risk or information based. It appears that individual samples taken under the NRCP testing programme may not always be taken as targeted samples, as specified under Council Directive 96/23/EC, but sometimes may be taken as random samples.

- There is a lack of sufficient cost-effective and reliable screening methods and/or the range of substances prescribed/covered by the testing is sometimes limited.

- There is limited flexibility to adopt emerging chemical substances into the NRCPs and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes. In addition, sampling under the NRCPs reflects only a part of testing done by a number of MSs, the results of which should be taken into consideration.

Conclusions on animal health and welfare

- As shown by the COMISURV quantitative assessment, the change from the current meat inspection system to a visual only system would cause a significant reduction in the capability of detection (detection fraction) and/or probability of detection during meat inspection for granulomatous lesions (including bovine tuberculosis), *Taenia saginata* cysticercosis, fasciolosis (primarily for mild cases) and respiratory diseases. The magnitude of this reduction was assessed by expert opinion, due to the lack of empirical data on performance of a visual only meat inspection.

- It is shown by the COMISURV quantitative analysis that a shift to visual only meat inspection would have an impact on the overall surveillance (meat inspection and clinical surveillance) for fasciolosis and bovine tuberculosis.

- The role of slaughterhouse meat inspection in bovine tuberculosis surveillance is of great relevance for the surveillance of *Mycobacterium bovis* infection in herds and animals.

- In non-OTF Member States and zones thereof, surveillance of bovine tuberculosis is based on both on-farm testing and identification of new infected herds by current meat inspection at the slaughterhouse. Meat inspection makes a substantial contribution to the overall detection of new breakdowns

- In OTF Member States and zones thereof, slaughterhouse meat inspection is the primary method of bovine tuberculosis surveillance, both for detection of residual *Mycobacterium bovis* infection, and for maintaining and substantiating infection prevalence below the limit established in EU legislation for granting and sustaining the OTF status.

- *Post-mortem* inspection is an important component of the overall bovine tuberculosis surveillance in both OTF and non-OTF Member States and zones thereof, and a reduction in the sensitivity of this component will substantially reduce surveillance quality. This effect may have the greatest impact in bovine tuberculosis surveillance in OTF Member States and zones thereof, which relies almost exclusively on surveillance by meat inspection.

- The quantitative assessment by COMISURV to determine the contribution of meat inspection to animal health surveillance in bovine animals concluded that the change from the current meat inspection to a visual only system would cause a fivefold reduction in the effectiveness

of detection of bovine tuberculosis, this effect being more prominent for early infection with small lesions.

- The quantitative model implemented to assess the impact of different meat inspection options on the overall sensitivity of a bovine tuberculosis surveillance system in OTF countries showed that a reduction in the sensitivity of bovine tuberculosis detection at individual (animal) level (due to the change to a visual only meat inspection) has a negative impact on the surveillance system sensitivity (i.e. the ability of the meat inspection surveillance system implemented in an area of interest to detect at least one positive herd when the prevalence is above the set threshold).

- The quantitative model showed that the difference in performance between the two meat inspection options (current or visual only) is mainly influenced by the slaughtering rate and the herd size, as these values determine the number of animals that are tested each year (*n*, the sample size). In fact, the smaller the proportion of animals sent to the slaughterhouse, the lower the overall sensitivity of the bovine tuberculosis surveillance system. This is why, when this proportion is low, only areas with a large number of herds will be able to reach the 95 % confidence.

- As the number of bovine herds in a given geographical area or country is a parameter not amenable to modification, this parameter becomes a limiting factor for the quality of the bTB surveillance. A reduction in meat inspection sensitivity arising from a change to a visual only system would affect the area sensitivity in such a way that several EU Member States:

  - Will not achieve a 95 % probability of detecting at least one positive herd when the true prevalence is above the threshold;

  - Will be unable to state with 95 % confidence that the true prevalence of positive herds is below the threshold (i.e. 0.001) given that all slaughtered animals tested negative during meat inspection.

  This is because the number of herds in the country is lower than a required value estimated by the model, assuming slaughtering rates of between 20 % and 40 %.

- Surveillance data for bovine cysticercosis are currently provided only through meat inspection at the slaughterhouse.

- The quantitative assessment carried out by COMISURV for this opinion found a significant decrease in effectiveness of detection of meat inspection when moving from the current to a visual only system for bovine cysticercosis, with a fourfold reduction in the detection fraction.

- The probable consequences of a further reduction in sensitivity if a visual only meat inspection were to be adopted would be an increase in the likelihood of transmission of *Taenia saginata* and, in turn, an increase in prevalence of the infection in bovine animals.

- Studies indicate that fasciolosis in cattle is underdiagnosed by clinical surveillance and that its prevalence, as determined by post-mortem meat inspection, can be high.

- The present *post-mortem* meat inspection procedure is the most effective tool in routine liver fluke surveillance in cattle, and a less sensitive, 'visual only' ,inspection of the liver would result in a reduction in the detection rate of liver fluke in individual bovine animals.

- Given the current prevalence of fasciolosis in cattle, it is unlikely that the reduction in animal-level sensitivity would significantly impact herd-level sensitivity (as it is unlikely that all infected cattle within a herd would be missed).

- The consequences to animal health and welfare of a change to visual only meat inspection for the monitoring of fasciolosis were not considered to be significant.

- The palpation and incision of the lungs and related tissues, as defined by legislation, improves the sensitivity of detecting respiratory lesions.

- Extended use of food chain information has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only *post-mortem* inspection is applied.

- Food chain information is a potentially effective tool to perform more targeted *ante-mortem* and *post-mortem* inspection tasks in the slaughterhouse which may increase the effectiveness of those tasks in detecting conditions of animal health and animal welfare significance.

- The existing ineffective flow of information from primary production to the slaughterhouses and vice versa reduces the ability to detect animal diseases and animal welfare conditions at the slaughterhouse and as a result limits possible improvements on animal health and welfare standards at the farm as farmers will not be aware of the slaughterhouse findings.

- None of the conclusions and recommendations on chemical hazards were considered to have an impact on animal health and welfare surveillance and monitoring.

TOR 3. ***If new hazards currently not covered by the meat inspection system (e.g.* Salmonella, Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.***

Conclusions on biological hazards

- Since none of the bovine meat-borne biological hazards categorised as of high-priority can be detected by traditional macroscopic meat inspection, other approaches are necessary to control these hazards. This can be best achieved using FCI and risk-based controls along the farm to chilled bovine carcass continuum.

- An integrated bovine meat safety assurance system has been outlined and includes the need for clear and measurable high-priority meat-borne hazard-based EU targets (hazard prevalence and/or concentration) to be achieved by Food Business Operators (FBOs) in/on bovine carcasses and, when appropriate, in bovine farms/herds.

- Risk-based targets derived from harmonised monitoring are not yet available for the bovine meat-borne biological hazards categorised as of high-priority for meat inspection (i.e. *Salmonella* spp. and pathogenic VTEC).

- An important element of an integrated bovine meat safety assurance system should be risk categorisation of farms/herds of bovine animals based on farm descriptors and historical data as well as herd-specific information, including monitoring of Harmonised Epidemiological Indicators (HEI) as described in the related Scientific Report of EFSA[4].

- Significant differences exist among bovine farms/herds in farming practices, risk factors and controls used in respect to *Salmonella* spp. and pathogenic VTEC, and thus potentially in the corresponding status of bovine animal batches sent to slaughter. This indicates that it should

[4] European Food Safety Authority, 2013. Technical specifications on harmonised epidemiological indicators for biological hazards to be covered by meat inspection of bovine animals. EFSA Journal 2013;11(6):3276, 78 pp. doi:10.2903/j.efsa.2013.3276

be possible to risk categorise bovine animal batches sent to slaughter for *Salmonella* spp. and pathogenic VTEC through use of FCI, based on farm/herd historical data, and information gathered through application of appropriate HEI.

- Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments (PHA) and from Hazard Analysis Critical Control Point (HACCP) programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

- High-risk animal batches or herds should be subjected to additional slaughter hygiene control measures and possibly complemented with decontamination treatments, or might be directed to slaughterhouses having demonstrated an enhanced ability to control carcass contamination. Where necessary, meat derived from carcasses of high risk animals may be used only for heat processed or cooked products. Animal batches of unknown risk category for a given hazard or mixed batches that include animals of unknown or high risk category for a given hazard should be handled as of high risk.

Conclusions on chemical hazards

- Dioxins and DL-PCBs which accumulate in food-producing animals have been ranked as being of high potential concern. As these substances have not yet been comprehensively covered by the sampling plans of the current meat inspection (NRCPs), they should be considered 'new' hazards.

- In addition, for a number of chemical elements used as feed supplements and for organic contaminants that may accumulate in food-producing animals, only limited data regarding residues in bovine animals are available. This is the case, in particular, for brominated flame retardants, including polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), as well as perfluorinated compounds (PFCs) including (but not limited to) perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

TOR 4. ***Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see annex 2 of the mandate). When appropriate, food chain information should be taken into account.***

Conclusions on biological hazards

- FCI can be improved by including information on participation in quality assurance schemes and by improved feedback to the primary producer, as this would likely result in the production of healthier animals.

- *Ante-mortem* inspection assesses the general health status of animals and helps in the detection of animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current visual inspection methods do not increase the microbiological risk to public health, no adaptations for the existing visual *ante-mortem* inspection are required or recommended.

- Visual *post-mortem* inspection of bovine carcasses can detect faecal contamination that may indicate potential exposure to the identified high-priority hazards. However, palpation/incision, as used in current *post-mortem* inspection, should be omitted in the case of bovine animals subjected to routine slaughter, because these procedures do not add to the identification and control of the high-priority bovine meat-borne hazards and may increase

their spreading and cross-contamination.

- Manual techniques of examination should be limited to suspect bovine animals and should be performed, where appropriate, separately from the slaughterline operation. Abnormalities on aesthetic/meat quality grounds can be eliminated through an adequate meat quality assurance system, which may also detect abnormalities associated with non-meat-borne and low-priority hazards, as well as related data recording and distribution.

Conclusions on chemical hazards

- Bovine farming in the EU is diverse, with substantial differences between intensively and extensively produced animals, and between veal calves and adult bovine animals, and consequently the types and likelihood of occurrence of chemical residues and contaminants will vary.

RECOMMENDATIONS

Recommendations on biological hazards

- Hazard identification and associated priority or risk ranking should be revisited regularly as new hazards might emerge and/or hazards that presently are of undetermined or low-priority might become more relevant in the future, in some regions, or as more data become available.

- To provide a better evidence base for future rankings the following should be undertaken: (i) systematic collection of data for source attribution of the identified bovine meat-borne hazards, and (ii) collection of data to identify and rank emerging bovine meat-borne hazards.

- All parties involved in the proposed integrated meat safety assurance system should be trained in the skills required.

- Research is needed on optimal ways of using the collected FCI data for risk categorisation of bovine farms/herds, as well as approaches for assessing public health benefits (e.g. by means of source attribution methods).

- For risk categorisation of slaughterhouses, baseline data collection and development of approaches for slaughterhouse PHA through use of indicator organisms are needed.

- In regions where *Salmonella* spp. is not controlled at farm level, preventive measures should be implemented in order to avoid its introduction in negative holdings or regions.

- Further research is needed on the extent to which manual manipulation during *post-mortem* inspection contributes to increasing spreading and cross-contamination of the high-priority hazards identified (i.e. *Salmonella* spp. and pathogenic VTEC) and possible methods to reduce this risk.

- The effect of the omission of palpation and incision on the meat safety risk posed by low-priority meat-borne hazard such as *Taenia saginata* cysticercosis and on the public health risk posed by non meat-borne hazards such as *Echinococcus granulosus* should be periodically re-visited in the future, particularly in those regions where those hazards are endemic.

Recommendations on chemical hazards

- Future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and the ranking of chemical substances into categories of potential concern.

- Regular updating of the ranking of chemical substances in bovine animals as well as of the sampling plans should occur, taking into account any new information regarding the toxicological profile of chemical residues and contaminants, usage in bovine animal production, and actual occurrence of individual substances as residues and contaminants in bovine animals.

- Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, and should also include 'new hazards'.

- There is a need for an improved integration of sampling, testing and intervention protocols for bovine animals across the food chain, NRCPs, feed control and monitoring of environmental contaminants.

- The development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into feed quality control and chemical residues and contaminants testing in the NRCPs.

- For prohibited substances, testing should be directed where appropriate towards the farm level. Future NRCP testing relating to substances that might be used illicitly for growth-promoting purposes needs to be refocused to better identify the extent of abuse in the EU. In addition, control measures for prohibited substances should not rely exclusively on NRCP testing, but should include veterinary inspection during the production phase and the use of biological methods and biomarkers suitable for the identification of abuse of such substances in bovine production in the EU.

Recommendations on animal health and welfare

- Animal based welfare indicators are available for on-farm welfare assessment of bovine animals, and these could be adapted to suit slaughterhouse conditions for effective *ante-mortem* detection of welfare conditions, including foot and leg disorders.

- Risk-based inspection procedures (including current or even more efficient *post-mortem* procedures) should be applied to skin test reactors to clarify the true *Mycobacterium bovis* infection status of the animal and of the herd. This is of greatest concern when bTB prevalence is low. Any change introduced in the current meat inspection should preserve this key element for bovine tuberculosis eradication.

- In order to avoid any reduction in the sensitivity of the overall surveillance system, meat inspection tasks aimed at detecting bovine tuberculosis as currently required by Regulation (EC) 854/2004 (palpation of the lungs and palpation and incision of retropharyngeal, tracheobronchial and mediastinal lymph nodes), should be retained.

- Current meat inspection is an important component of bovine tuberculosis surveillance, and the impact of any proposed changes in meat inspection protocols needs first to be assessed in the framework of the overall bovine tuberculosis surveillance strategy of the EU, to avoid a reduction in overall surveillance effectiveness. This is particularly important in OTF countries where field surveillance has ceased.

- If a visual only meat inspection system were to be adopted, alternative procedures should be applied that provide equivalent or even increased capability of detection than current meat inspection for bovine cysticercosis. At the meat inspection level there is preliminary evidence that masseter muscle incisions could be substituted by intensified inspection of the heart by practising additional incisions, compensating to a large extent for the loss in surveillance sensitivity.

- Lack of feedback of *post-mortem* results to the farmer prevents instigation of a liver fluke management programme, which could be detrimental to animal health and welfare. An improvement in this feedback of information is recommended as part of an effective meat inspection system.

- For respiratory diseases, an improved data collection and feedback system to primary producers is recommended.

- Animal based welfare indicators have been developed for the on-farm assessment of lameness in bovine animals (dairy cows) and could be adapted for use during routine *ante-mortem* inspection in slaughterhouses.

- Food chain information should include animal welfare status in order to complement the slaughterhouse surveillance systems (*ante-mortem* and *post-mortem* inspection) and the latter could be used to identify on-farm welfare status.

- An integrated system should be developed whereby food chain information for public health and for animal health and welfare can be used in parallel, more effectively.

- Provide farmers with background information on the animal diseases and welfare conditions of key concern that may affect their livestock and why it is important to provide this information to the slaughterhouse through the use of food chain information.

- The value of the FCI in guiding risk management to discriminate between animals subsequently going through different types of inspection procedures should be evaluated. Priority should be given to improving test sensitivity, noting that (pre-) screening tests should preferably produce few false negative classifications for the sake of animal disease detection and surveillance. Test specificity will largely be an economical parameter, since the subsequent inspection of all 'FCI –positive' animals or groups should detect any false positives not correctly identified during the FCI pre-screening.

APPENDICES

Appendix A: Assessment on biological hazards

SUMMARY

This Appendix of the Scientific Opinion deals with the biological human health hazards to be covered by meat inspection of bovine animals. The mandate included four terms of reference which in summary required: (1) the identification and priority ranking (for meat inspection) of the main biological risks for public health associated with the handling and preparation at the time prior to consumption and/or consumption of meat from bovine animals; (2) an assessment of the strengths and weaknesses of current meat inspection; (3) recommendations on how the current meat inspection should be improved to cover identified high-priority hazards that are not addressed by current meat inspection practices; and (4) recommendations on adaptations to current meat inspection methods and/or frequencies of inspections that may be used by risk managers if they consider that current methods are disproportionate to the risk of the hazards they address.

The mandate from the European Commission requested two opinions, one covering bovine animals under six weeks old and the other covering bovine animals over six weeks old. It was determined that within a true risk-based meat inspection concept, it is not necessary to design and apply a separate meat inspection system for individual bovine species or farming systems or animal age categories. Rather, a universal meat inspection framework can be designed and applied that would allow risk categorisation of animals based on individual farm-related food chain information (FCI), which also includes farming system and animal age category components. Thus, this justifies why a single Scientific Opinion for bovine animals is issued and not two different ones for the two different age groups as originally requested.

All hazards for which any evidence of bovine-meat-borne transmission exists and which may currently be present in the EU bovine animal population were considered. A decision tree was developed and used for priority ranking bovine animal meat-borne biological hazards. Hazards that are introduced and/or for which the risk for public health requires bacterial growth during processing steps after carcass chilling (*Listeria monocytogenes*, and toxins of *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus aureus*) were excluded at the first stage of the ranking and not considered further. The priority ranking was based on the assessment of: (i) the magnitude of the human health impact based on reported incidence, (ii) the severity of the disease in humans based on fatalities among reported cases, and (iii) the strength of evidence that meat from bovine animals is an important risk factor for the disease in humans. Based on the limited data available and expert opinion employed for the ranking, biological hazards categorised as low-priority for bovine meat inspection were *Bacillus anthracis, Campylobacter* spp. (thermophilic), *Sarcocystis hominis* and *Taenia saginata*. These hazards were not considered further because it was determined that the low-priority ranking was not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures).).However, the effect of carcass chilling on reduced survival of *Campylobacter* spp. (thermophilic) on carcasses of bovine animals as a non-hazard-specific control measure has to be taken into account.

Bovine meat-borne biological hazards categorised as of high-priority for meat inspection were *Salmonella* spp. and pathogenic verotoxigenic *Escherichia coli* (pathogenic VTEC). *Toxoplasma gondii* and extended spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene carrying *E. coli* were carachterised as of 'undetermined' priority for bovine meat inspection because the data available were insufficient for conclusive ranking. It should be noted that the ranking of biological hazards into specific categories is based on current knowledge and available data, and therefore ranking should be updated regularly when new information and data become available and including 'new hazards'.

The main elements of the current bovine meat inspection system include analysis of FCI, *ante-mortem* examination of animals and *post-mortem* examination of carcasses and organs. The assessment of the strengths and weaknesses of the current meat inspection was primarily focused on its contribution to the control of the identified high-priority bovine meat-borne biological hazards.

Strengths identified for the current meat inspection system were that, in principle, adequate collection and proper utilisation of FCI can be useful and beneficial in *ante-* and/or *post-mortem* bovine meat inspection. FCI, used as part of *ante-mortem* inspection, provides information related to veterinary treatments and disease history during animal rearing and helps focus *ante-mortem* and/or *post-mortem* meat inspection on animal and public health concerns. *Ante-mortem* and *post-mortem* inspection of bovine animals and carcasses enable detection of visible abnormalities, providing important benefits in monitoring animal health and welfare. *Ante-mortem* inspection of bovine animals enables animal identification for traceability, and can be used to verify FCI given by the farmer and to provide feedback to producers on problems detected, but usually for issues not related to public health. *Ante-mortem* visual examination detects bovine animals with diarrhoea as well as visible faecal contamination that may be associated with increased risk of microbial cross-contamination during slaughter. *Post-mortem* inspection detects visual faecal contamination on dressed bovine carcasses that may indicate potential exposure to the identified high-priority bovine meat-borne hazards.

A number of weaknesses were also identified for the existing bovine meat inspection system. Currently, FCI collection is not harmonised, is used only to a limited extent, and is not adequate to allow classification of bovine farms/herds in relation to potential presence of the identified high-priority bovine meat-borne biological hazards *Salmonella* spp. and pathogenic VTEC. Current *ante-mortem* and *post-mortem* macroscopic inspection are not able to detect any of the identified high-priority bovine meat-borne biological hazards. Judgement of the fitness of bovine meat for human consumption by current *post-mortem* inspection does not differentiate food safety aspects from meat quality aspects, prevention of animal diseases, and occupational hazards. Manual handling of meat, including use of palpation/incision techniques, during *post-mortem* inspection does not contribute to the detection of the identified high-priority bovine meat-borne hazards; in fact, it may increase and spread these hazards by cross-contamination.

Since none of the bovine meat-borne biological hazards categorised as of high-priority can be detected by traditional macroscopic meat inspection, other approaches are necessary to control these hazards. This can be best achieved using FCI and risk-based controls along the farm to chilled bovine carcass continuum. Consequently, an integrated bovine meat safety assurance system has been outlined and includes the need for clear and measurable high-priority meat-borne hazard-based EU targets (hazard prevalence and/or concentration) to be achieved by Food Business Operators (FBOs) in/on bovine carcasses and, when appropriate, in bovine farms/herds. Risk-based targets derived from harmonised monitoring are not yet available for the bovine meat-bone biological hazards categorised as of high-priority for meat inspection (i.e. *Salmonella* spp. and pathogenic VTEC).

An important element of an integrated bovine meat safety assurance system should be risk categorisation of farms/herds of bovine animals based on farm descriptors and historical data as well as herd-specific information, including monitoring of Harmonised Epidemiological Indicators (HEI) as described in the related Scientific Report of EFSA[5]. Significant differences exist among bovine farms/herds in farming practices, risk factors and controls used in respect to *Salmonella* spp. and pathogenic VTEC, and thus potentially in the corresponding status of bovine animal batches sent to slaughter. This indicates that it should be possible to risk categorise bovine animal batches sent to slaughter for *Salmonella* spp. and pathogenic VTEC through use of FCI, based on farm/herd historical data, and information gathered through application of appropriate HEI.

[5] European Food Safety Authority, 2013. Technical specifications on harmonised epidemiological indicators for biological hazards to be covered by meat inspection of bovine animals. EFSA Journal 2013;11(6):3276, 78 pp. doi:10.2903/j.efsa.2013.3276

Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments (PAH) and from Hazard Analysis Critical Control Point (HACCP) programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance. High-risk animal batches or herds should be subjected to additional slaughter hygiene control measures and possibly complemented with decontamination treatments, or might be directed to slaughterhouses having demonstrated an enhanced ability to control carcass contamination. Where necessary, meat derived from carcasses of high risk animals may be used only for heat processed or cooked products. Animal batches of unknown risk category for a given hazard or mixed batches that include animals of unknown or high risk category for a given hazard should be handled as of high risk.

Regarding potential adaptations of current meat inspection procedures, FCI can be improved by including information on participation in quality assurance schemes and by improved feedback to the primary producer, as this would likely result in the production of healthier animals. *Ante-mortem* inspection assesses the general health status of animals and helps in the detection of animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current visual inspection methods do not increase the microbiological risk to public health, no adaptations for the existing visual *ante-mortem* inspection are required or recommended. Visual *post-mortem* inspection of bovine carcasses can detect faecal contamination that may indicate potential exposure to the identified high-priority hazards. However, palpation/incision, as used in current *post-mortem* inspection, should be omitted in the case of bovine animals subjected to routine slaughter, because these procedures do not add to the identification and control of the high-priority bovine meat-borne hazards and may increase their spreading and cross-contamination.

Manual techniques of examination should be limited to suspect bovine animals and should be performed, where appropriate, separately from the slaughterline operation. Abnormalities on aesthetic/meat quality grounds can be eliminated through an adequate meat quality assurance system, which may also detect abnormalities associated with non-meat-borne and low-priority hazards, as well as related data recording and distribution.

A series of recommendations are made in relation to biological hazards, mainly on data needs for future hazard identification and priority or risk ranking exercises and on the need for ways to risk categorise bovine farms/herds and to carry out PHA of slaughterhouses through the use of indicator organisms.

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ASSESSMENT

1. Introduction: definition of meat inspection and scope of the Opinion

A previous EFSA Scientific Opinion on public health hazards addressed by meat inspection of swine described various interpretations (based on the EU legal framework and on international codes of practice) of what constitutes meat inspection (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011). It concluded: "*the definition of the term meat inspection is probably somewhat intuitive and based more on procedures of practical application than on specific or formal definition or description of its purpose*".

Under the EU regulatory framework, Regulation (EC) No 854/2004 (as amended) lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption and describes the main principles of Food Chain Information (FCI), *ante-mortem* and *post-mortem* inspection. In particular, this EU regulation prescribes certain meat inspection procedures specific to bovine animals. At the same time, specific inspection procedures are described to address zoonotic animal diseases such as cysticercosis, tuberculosis and brucellosis.

Following discussions with the European Commission and in line with the approach taken in related previous EFSA Opinions (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011 and 2012), the following need to be taken into account in order to understand the scope of this Appendix of the overall EFSA Scientific Opinion on meat inspection of bovine animals:

1. The intention of this Appendix is to: (i) identify and rank the currently most relevant bovine meat-borne biological risks (i.e. term of reference (TOR) 1); (ii) assess the strengths and weaknesses of the current meat inspection system (i.e. TOR 2), and (iii) outline a generic framework for meat safety assurance relative to the priority hazards not covered by the current meat inspection (i.e. TORs 3 and 4).

2. The following are outside the scope of this document:

    a. transmissible spongiform encephalopathies (TSEs);

    b. issues other than those of public health significance, but which still compromise fitness of meat for human consumption (Regulation (EC) No 854/20046, Annex I, Section II, Chapter V), for example quality issues such as dark firm and dry (DFD) meat;

    c. biological hazards and controls associated with stages of the meat chain beyond the chilled carcass in the case of cold boning or the final carcass before hot boning;

    d. biological hazards and proposed changes to meat inspection procedures representing primarily occupational health risks;

    e. potential implications of inspection changes on the environment; and

    f. private slaughter.

[6] Regulation (EC) No 854/2004 of the European Parliament and of the Council of 30 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. OJ L 139, 30.4.2004, p. 206. Corrigendum, OJ L 226, 25.6.2004, p. 83–127.

3. The TORs also stated that, where relevant, and should available data so permit, distinction will be made when addressing the different terms of reference between:

   a. different bovine species (e.g. *Bos taurus*, *Bubalus bubalis* and *Bison bison*); and

   b. animal production practices and slaughter procedures (e.g. dairy vs. beef; intensive vs. extensive farming; integrated vs. non-integrated farming; religious slaughter vs. non-religious slaughter).

   However, in the risk-based approach to meat safety assurance used in this document, these aspects (i.e. species, age, farming system, slaughter system) were not considered separately (i.e. in isolation), but rather were considered together with other risk factors analysed within the FCI and used for risk categorisation of incoming animals and/or slaughterhouses (see Section 4). Subsequently, the risk categories of incoming animals/slaughterhouses would determine the nature of meat safety assurance, including meat inspection, to be applied in a given situation.

4. Age is not considered as a universal or unique factor, but it is addressed if relevant to specific hazards. This includes considerations given to bovine animals younger and older than six weeks of age (which was specified in the mandate) and to differences in age-related current meat inspection practices. Thus, this justifies why a single Scientific Opinion for bovine animals is issued and not two different ones for the two different age groups as originally requested.

5. Chemical hazards and associated bovine meat safety risks were considered by the CONTAM Panel and are reported in a separate part of this Opinion (see Appendix B).

6. The highest priority is given to public health objectives through proposed improvements in the biological meat safety inspection system. Any implications of proposed inspection changes on animal health and animal welfare were assessed by the AHAW Panel (see Appendix C).

7. Issues related to harmonised epidemiological criteria and associated sampling/testing methodologies for hazards dealt with in this Appendix are addressed by the Biological Monitoring Unit (BIOMO) in a separate Scientific Report of EFSA (EFSA, 2013).

There are two further documents on bovine meat inspection and slaughter practices in the EU that should also be considered as background information to this Appendix:

- A Scientific Report submitted to EFSA on the overview of the current practices of meat inspection in the EU (DAFC, 2011). This report provides useful background information on bovine meat inspection and slaughter practices in the EU; and

- An Event Report on the technical hearing with stakeholders organised by EFSA on bovine meat inspection on 25 May 2012 (EFSA, 2012).

2. Hazard Identification and risk ranking

2.1. Hazard identification

2.1.1. Methodology

A food-borne hazard is defined by the Codex Alimentarius Commission (CAC) as a "*biological, chemical or physical agent or property of food with the potential to cause an adverse health effect*" (CAC, 1999).

The first step in the hazard identification process, carried out as part of this risk ranking activity, focused on identifying biological hazards occurring in bovine animals and/or contaminated bovine meat that can be transmitted to humans, in whom they may cause disease. As a starting point, the hazards presented in a previous EFSA Scientific Opinion that had addressed the food safety aspects of dairy cow housing and husbandry systems were considered (EFSA, 2009a). That Scientific Opinion provided a list of the main biological hazards associated with dairy cow farming based on a review of several scientific publications (Roginski et al., 2002; Klinth-Jensen et al., 2004; Bohm et al., 2007; Cavirani, 2008; Buncic et al., 2009). Further, additional hazards included in the preliminary list developed were derived from reviews of textbooks, the peer-reviewed scientific literature and technical documents, and when all other evidence was lacking, based on expert opinion of the BIOHAZ Panel and other Experts involved in the meat inspection of bovine meat working group. This led to the development of a preliminary **long list** of biological hazards (Table 1).

Each of the biological hazards included in this preliminary (long) list was examined as to whether it met the following two criteria, in sequence, following an approach similar to that employed in earlier EFSA meat inspection Opinions (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012):

- **Bovine meat-borne criterion:** Is there any evidence that the hazard can be transmitted to humans through handling, preparation and/or consumption of bovine meat? In the context of this opinion, *handling and preparation* are interpreted as handling of bovine meat by consumers or professional food handlers during preparation immediately prior to consumption.

- **EU relevance criterion:** Is there evidence that the hazard is present in the EU bovine animal population?

Those hazards from the preliminary long list that met both above criteria were included in a final **short list** of hazards to be considered in following steps of this assessment.

2.1.2. Results of hazard identification

2.1.2.1. Preliminary long list of biological hazards

Following the methodology explained above, the biological hazards included in the preliminary **long list** of hazards are presented in Table 1. Each of these hazards was assessed with respect to the two criteria described earlier (i.e. bovine meat-borne transmission criterion and presence in the EU bovine animal population criterion).

Table 1: Preliminary **long list** of biological hazards and the result of the assessment against the two criteria (i.e. evidence that hazard is bovine meat-borne and is present in the EU bovine population).

Biological hazard	Any evidence of bovine meat-borne transmission?	Currently present in the EU bovine population?	Included in short list for priority ranking?	Examples of recent supporting evidence for inclusion
Bacteria				
Actinobacillus lignieresii	No. Contact infection	NA[1]	No	NA
Aeromonas hydrophila	No. Contaminated water, contact infection. Food-borne transmission not established	NA	No	NA
Anaplasma phagocytophilum	No. Vector-borne	NA	No	NA
Arcanobacterium pyogenes	No. Contact infection	NA	No	NA
Arcobacter spp. (formerly mesophilic *Campylobacter* spp.)	No. Rarely human pathogen. Food-borne transmission not established	NA	No	NA
Bacillus anthracis	**Yes**	**Yes**	**Yes**	(Popescu et al., 2011; OIE, 2013)
Bacillus cereus	**Yes**	**Yes**	**Yes**	(Magnusson et al., 2007; EFSA and ECDC, 2012a)
Bartonella spp.	No. Vector-borne (bites and scratches)	NA	No	NA
Borrelia burgdorferi	No. Vector-borne (ticks)	NA	No	NA
Brucella abortus	No. Contact infection; can be food-borne (primarily milk)	NA	No	NA
***Campylobacter* spp. (thermophilic)**	Yes. Food-borne, including meat from bovine animals	**Yes**	**Yes**	(EFSA and ECDC, 2012a)
Clostridium botulinum	**Yes**	**Yes**	**Yes**	(EFSA, 2009a; Lindstrom et al., 2010)
Clostridium difficile	No. Nosocomial infection. Present in meat; meat-borne transmission not established	NA	No	NA
Clostridium perfringens	**Yes**	**Yes**	**Yes**	(Lebrun et al., 2010; Grass et al., 2013)
Corynebacterium spp.	No. Contact infection, food-borne via milk	NA	No	NA

Biological hazard	Any evidence of bovine meat-borne transmission?	Currently present in the EU bovine population?	Included in short list for priority ranking?	Examples of recent supporting evidence for inclusion
Coxiella burnetii[2]	No. Aerosols; shed in milk but not considered food-borne	NA	No	NA
Dermatophilus congolensis	No. Contact infection	No	No	NA
Fusobacterium necrophorum	No. Contact infection	NA	No	NA
Pathogenic VTEC[3]	**Yes**	**Yes**	**Yes**	(EFSA, 2007a; EFSA and ECDC, 2013)
Extended spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene-carrying bacteria	**Yes,** indirect evidence	**Yes**	**Yes**	(EFSA Panel on Biological Hazards, 2011a; EFSA and ECDC, 2012b; SSI and DTU, 2012)
Erysipelothrix rhusiopathiae	No. Contact infection	NA	No	NA
Leptospira hardjo	No. Contact infection; aerosols	NA	No	NA
Listeria monocytogenes	**Yes**	**Yes**	**Yes**	(EFSA and ECDC, 2012a; ProSafeBeef, 2012)
Mannheimia haemolytica	No. Contact infection	NA	No	NA
Mycobacterium avium subsp. *avium*	No. Bovine meat-borne transmission not established	NA	No	NA
Mycobacterium avium subsp. *paratuberculosis*[4]	No. Food-borne transmission not confirmed	NA	No	NA
Mycobacterium bovis[5]	No. Aerosols, food-borne via milk; no evidence of meat-borne transmission in the EU	NA	No	NA
Mycoplasma bovis	No. Aerosols	NA	No	NA
Pasteurella multocida	No. Contact infection	NA	No	NA
***Salmonella* spp. (non-typhoid)**	**Yes**	**Yes**	**Yes**	(EFSA and ECDC, 2012a)
Staphylococcus aureus	**Yes**	**Yes**	**Yes**	(Mork et al., 2012)
Meticillin-resistant *S. aureus*	No. Contact infection	NA	No	NA
Streptococcus zooepidemicus	No. Contact infection mainly. Food-borne, including milk from bovine animals	NA	No	NA

Biological hazard	Any evidence of bovine meat-borne transmission?	Currently present in the EU bovine population?	Included in short list for priority ranking?	Examples of recent supporting evidence for inclusion
Yersinia enterocolitica[5]	No. Food-borne, including milk from bovine animals	NA	No	NA
Yersinia pseudotuberculosis[5]	No. Food-borne, including milk from bovine animals	NA	No	NA
Viruses				
Bovine papillomavirus	No. Contact infection	NA	No	NA
Encephalitis virus (TBEV from family Flaviridae)	No. Vector-borne (ticks)	NA	No	NA
Lyssavirus (rabies)	No. Contact infection, primarily through animal bites	NA	No	NA
Parapox virus (pseudocowpox)	No. Contact infection	NA	No	NA
Parasites				
Cryptosporidium parvum[5]	No. Food and water-borne, bovine meat-borne transmission not established	NA	No	NA
Echinococcus granulosus	No. Ingestion of material containing contaminated canine faeces	NA	No	NA
Dicrocoelium dendriticum	No. Ingestion from contaminated environment	NA	No	NA
Fasciola hepatica	No. Ingestion from contaminated environment	NA	No	NA
Giardia duodenalis[5]	No. Food and water-borne, bovine meat-borne transmission not established	NA	No	NA
Sarcocystis hominis	**Yes.** Only meat from bovine animals	**Yes**	**Yes**	(FERA et al., 2010b)
Taenia saginata	**Yes.** Only meat from bovine animals	**Yes**	**Yes**	(EFSA and ECDC, 2012a)
Toxoplasma gondii[6]	**Yes**	**Yes**	**Yes**	(Halos et al., 2011; EFSA and ECDC, 2012a)

Biological hazard	Any evidence of bovine meat-borne transmission?	Currently present in the EU bovine population?	Included in short list for priority ranking?	Examples of recent supporting evidence for inclusion
Fungi				
Trichophyton verrucosum (Ringworm)	No. Contact infection	NA	No	NA

[1] NA = not applicable, as the hazard already does not comply with the bovine meat-borne transmission criterion.
[2] Recently reviewed by EFSA in the Scientific Opinion from the EFSA Panel on Animal Health and Welfare on Q Fever. EFSA Journal 2010; 8(5):1595.
[3] Human pathogenic verocytotoxin-producing *E. coli*, also known as verotoxigenic *E. coli*, verocytotoxigenic *E. coli*, verotoxin-producing *E. coli* and Shiga toxin-producing *E. coli* (STEC).
[4] *M. avium* subsp. *paratuberculosis* was not considered further because its zoonotic potential is the subject of current scientific debate and has not yet been established.
[5] Details on the assessment of the bovine meat-borne transmission potential of these hazards are presented in Annex A.
[6] Based also on results of an study funded by the French Agency for Food, Environmental and Occupational Health and Safety that were kindly presented by Dr Radu Blaga during the meeting of the working group drafting the Scientific Opinion on 4 December 2012. See Section 2.2.3.2. below for details of the data presented at that meeting.

2.1.2.2. Final short list of hazards

The resulting final **short list** of identified hazards to be dealt with in the risk assessment section of this Opinion, as shown in Table 2, consists of established biological hazards occurring in bovine animal species in the EU and potentially transmitted through the handling, preparation (immediately prior consumption) and/or consumption of meat from bovine animals in the EU.

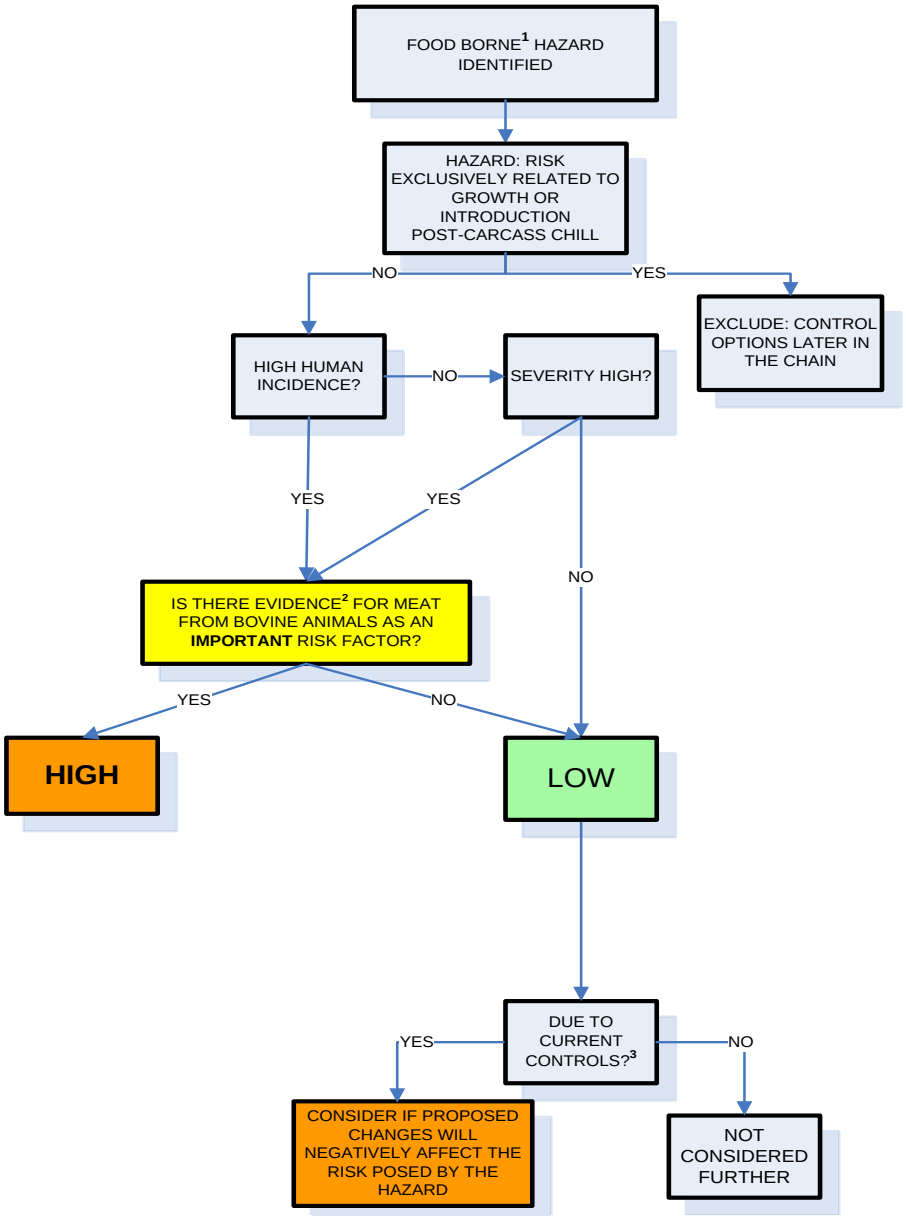
Table 2: Final **short list** of biological hazards that can be transmitted to humans through bovine meat in the EU and that can be present in the bovine animal carcass at post-chill.

`	**General mechanism of human disease**
Bacteria	
Bacillus anthracis	Pulmonary, gastrointestinal or cutaneous infection
B. cereus	Toxicoinfection (diarrheal) including meat-borne; intoxication (emetic) due to starchy foods
Campylobacter spp. (thermophilic)	Gastrointestinal and rarely invasive infection
Clostridium botulinum (non-infant)	Intoxication after multiplication in foods
C. perfringens	Toxicoinfection after multiplication in foods
Listeria monocytogenes	Invasive infection after post-processing introduction and multiplication in ready-to-eat foods
Pathogenic VTEC	Toxicoinfection
ESBL/AmpC gene-carrying bacteria	Antimicrobial-resistant infection
Salmonella spp.	Gastrointestinal and invasive infection
Staphylococcus aureus	Intoxication after multiplication and toxin formation in foods
Parasites	
Sarcocystis hominis	Gastrointestinal infection
Taenia saginata	Gastrointestinal infection
Toxoplasma gondii	Invasive infection

2.2. Priority ranking

2.2.1. Methodology

Each hazard was ranked according to the priority that should be given to it when considering if it should be addressed by meat inspection. This priority ranking was carried out employing a decision tree (Figure 1) adapted from the one presented in the Scientific Opinion on poultry meat inspection (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012):



[1] In the context of this opinion, food-borne is defined as transmission of the hazard through the *handling, preparation and/or consumption* of bovine meat. *Handling and preparation* are interpreted as handling of bovine meat by consumers or professional food handlers during preparation immediately prior to consumption.

[2] Evidence based on (i) epidemiological link, (ii) carcass prevalence/farm-level prevalence, (iii) comparative considerations with meat from other species and (iv) expert opinion. For details, see the text below.

[3] Current controls: any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures.

Figure 1: Decision tree used in priority ranking of identified bovine meat-borne hazards.

This decision tree differs from that employed in the former EFSA Opinion on public health hazards to be addressed by meat inspection of poultry in the following:

- The term '**priority'** has substituted the term 'risk' which was previously employed. This is because, in order to carry out an informed risk ranking at EU level, sufficient and robust data should be available on both the occurrence of the relevant hazards and on the attributable fraction of the different hazard-meat-species combinations to human disease. In the former EFSA Opinions on inspection of swine and poultry meat, there were sufficient data available at EU level for the relevant hazards (i.e. EU-wide baseline surveys, harmonised monitoring) that aided the risk ranking process. It was determined that in the absence of sufficient EU-wide data for bovine meat, it would be more appropriate to adopt the word 'priority' (for inspection), rather than 'risk', when categorising the relevance of the different hazards.

- Carcass pathogen prevalence and source attribution are not considered as separate questions, or ranking steps, in the modified decision tree. They are addressed together in a single step, as follows: "*is there evidence for meat from bovine animals as an important risk factor?*". This modification was considered necessary due to the lack of sufficient data at EU level for robustly qualifying carcass prevalence and source attribution for the given hazards in the case of bovine meat. Furthermore, meat from bovine animals is consumed less extensively in the EU than meat from swine and chickens. Therefore, attribution at population level, as applied in the previous opinions, may not provide a sufficiently detailed perspective on the relative risk of different hazards in bovine meat. Thus, other aspects related to the risk to individual consumers rather than the population as a whole, are taken into account. The criteria to be considered in answering this question in this new combined step are described below.

As a consequence of these modifications, the steps of the decision tree (Figure 1) are now described as follows:

- Step 1: Identifies and excludes those **hazards that are introduced and/or for which the risk for public health requires growth during steps following carcass chilling**. The reasons for excluding such hazards from further assessment were that meat inspection provides no control of the public health outcome of those hazards, specifically:

    i. The scope and target of meat inspection are focused on hazards present on the final bovine carcass at the end of slaughter in chilled for cold boning, or on the final carcasses before hot boning, and always before further processing of carcasses or meat, which may lead to an adverse public health outcome.

    ii. Hazards introduced after carcass chilling and those for which the public health risk is the result of growth during post-chilling processes or steps are better controlled later in the food-production chain through various interventions and Hazard Analysis and Critical Control Points-based control programs (HACCP).

- Step 2: Assesses the **magnitude of the human health impact based on incidence**, as measured by the notification rate or reported number of illness cases. Incidence was considered high if the notification rate in humans at EU level, as reported to ECDC, was equal to or higher than 10 cases in 100 000 population in any given year. No correction for underreporting or underascertainment was made.

- Step 3: Assesses the **severity of the disease in humans based on mortality**. This was measured as the percentage of deaths among confirmed cases with information on death available. Severity was also evaluated by comparing the disease burden, expressed in Disability Adjusted Life Years (DALY) per 1 000 cases. The DALY metric quantifies the impact of disease on health-related quality of life of acute diseases and sequelae (Years Lived

with Disability, YLD), as well as the impact of premature deaths (Years of Life Lost, YLL). Severity was considered high if mortality in humans at EU level, as reported to ECDC, was higher or equal to 0.1 % in more than one year or if the disease burden was higher or equal to 100 DALYs per 1 000 cases (based on estimates from the Netherlands in 2009). This step of the decision tree was not considered if the magnitude of the human health impact based on incidence (step 2) was determined to be high.

- Step 4: Evaluates **strength of evidence** that meat from bovine animals is an important risk factor. This is determined based on the following criteria considered in priority order (recent data or studies from within the EU/European Economic Area (EEA) are preferred, but in their absence other relevant sources of data or information could be considered):

  i. Epidemiological link, based on a significant association of consumption of meat from bovine animals as a risk factor for human cases, or on outbreak data,

  ii. Carcass prevalence / Farm level prevalence (from prevalence studies),

  iii. Comparative considerations for meat from related species, and

  iv. Expert opinion whether bovine meat consumption is a risk factor.

The final outcome of the process (Figure 1) is placement of each hazard in one of two priority categories ('High' or 'Low') defined as follows:

- The priority was characterised as '**High**' when: a hazard was identified as a high incidence of illness in humans and there was strong evidence for the consumption, handling and/or preparation[7] of bovine meat being an important risk factor; when the incidence of the hazard was low its priority was considered high if the severity of the disease is high and there was strong evidence for bovine meat being an important risk factor. Considering the limitations of the data available for the priority ranking, this priority category could be regarded as combining both the medium and high risk categories of the risk ranking carried out in the former poultry meat inspection Opinion.
- The priority was characterised as '**Low**' when: a hazard was identified as a high incidence of illness in humans but there was no confirmed evidence for bovine meat being an important risk factor, irrespective of the severity of human disease; the incidence of the hazard was low in humans and the severity high but there was no evidence for bovine meat being an important risk factor; and when the incidence of the hazard in humans was low and the severity was also low irrespective of evidence for bovine meat being an important risk factor.

Further the priority was characterised as '**Undetermined'** if the data available for the assessment of a given biological hazard was insufficient to conclude on the ranking.

For all hazards placed in the low-priority category, it was further assessed (see flow after 'Low' in Figure 1) if falling into this category was due to currently applied controls (i.e. any hazard-specific control measure implemented at farm and/or slaughter level before chilling of the carcass, including meat inspection procedures). If that was not the case, the hazard was not considered further. However, if that was the case then it was evaluated if any proposed changes to current meat inspection procedures would increase the risk posed by the hazard, and whether the extent of the increase would require re-categorisation of the hazard into the high-priority category or it would still remain in the low-priority category.

7 In the context of this opinion, *handling and preparation* should be interpreted as handling of bovine meat by consumers or professional food handlers during preparation immediately prior to consumption.

2.2.2. Data employed for the priority ranking of the hazards

2.2.2.1. Human disease data in the EU

Data, presented in Table 3, supplied by the European Centre for Disease Prevention and Control (ECDC) from The European Surveillance System (TESSy), cover the years 2008 to 2011. The data were supplied as aggregates for all EU reporting Member States (MSs), without specifying particular countries. The data supplied are reliable, albeit incomplete, since some countries did not report on certain diseases and no corrections for underascertainment and underreporting were made.

Table 3: Incidence and severity estimates based on available overall notification rate in humans and deaths as reported by EU MSs from 2008 to 2011 according to Decision (2119/98/EC) on communicable diseases for the biological hazards of bovine origin identified to be transmissible to humans through consumption of bovine meat. TESSy data extraction carried out on 31 January 2013. Data in this table may vary from those presented in former related EFSA Opinions (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012) due to updates provided by the MSs to retrospective TESSy data. Definition of confirmed case available in Commission Implementing Decision 2012/506/EU of 8 August 2012.

Selected hazard	Incidence in humans (number of reported confirmed cases per 100 000 EU population[1]; [number of confirmed cases])				Severity in humans (percentage of reported deaths; [number of confirmed cases with information])			
	2008	2009	2010	2011	2008	2009	2010	2011
Bacillus anthracis	<0.01 [2]	<0.01 [14]	0.01 [32]	<0.01 [6]	100.00 [1]	54.55 [11]	37.93 [29]	25.00 [4]
Campylobacter spp. (thermophilic)[2]	62.00 [190577]	64.19 [198682]	69.37 [215058]	71.53 [215801]	0.03 [109671]	0.02 [109718]	0.03 [117367]	0.04 [116292]
VTEC (all serogroups)[3]	0.86 [3 156]	0.97 [3583]	1.00 [3656]	2.56 [9478]	0.15 [1363]	0.35 [1701]	0.38 [2108]	0.75 [7504]
VTEC (O157)[4]	0.35 [1683]	0.39 [1888]	0.31 [1510]	0.45 [2195]	0.00 [241]	0.94 [318]	0.56 [536]	0.36 [1110]
Salmonella spp.[5]	29.46 [132800]	23.81 [108977]	21.51 [99590]	20.37 [94264]	0.09 [72837]	0.08 [54273]	0.13 [46996]	0.12 [46808]
ESBL/AmpC gene-carrying *E. coli*[6]	NA	NA	NA	0.03 [118]	NA	NA	NA	0.00 [11]
Toxoplasma gondii (congenital cases, i.e. in infants <1 year)[7]	0.04 [83]	0.10 [306]	0.07 [279]	0.01 [29]	50.00 [2]	9.62 [260]	5.15 [233]	NA

1 EU population data based on individual MS population sizes reported in EUROSTAT (data extracted: September 2012). When the given hazard was not reported by a MS to TESSy, the population size reported by that MS was also taken out of the calculation of the overall EU population size.

2 Portugal, Greece not reporting

3 Portugal not reporting. For a more detailed review of VTEC (including serotype O157) incidence and severity in the EU see the recently published EFSA Opinion on VTEC-seropathotype and scientific criteria regarding pathogenicity assessment (EFSA BIOHAZ Panel on Biological Hazards, 2013).

4 Portugal not reporting

5 *Salmonella* Typhi and *S.* Paratyphi not included; Netherlands not reporting

6 Only Belgium, Hungary, Netherlands and Slovenia reporting

7 Belgium, Denmark, Greece, Italy, Netherlands, Portugal and Sweden not reporting; Spain reporting through sentinel system and thus not taken into account. France not reported in 2011 at the time of extraction of these data.

8 NA = not available

The data supplied are for the years 2008, 2009, 2010 and 2011, and are officially reported to ECDC (TESSy) by 27 EU MSs, in accordance with Commission Implementing Decision of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council; however, some MS do not report on certain diseases (for details see footnotes to Table 3). The data were supplied as aggregates from all reporting MSs. The cases reported are not necessarily associated with specific food attributions since in most cases it is not possible to confirm this link. The data show notification rates of confirmed human disease cases per 100 000 population, and severity of illness in humans as number of reported deaths as a percentage of confirmed cases for which information is available. Cases include all reported confirmed occurrences of the disease, regardless of the origin of the infection. In fact, establishing the food-related origin of infection is often not possible and seldom reported. The data on severity include, as a proxy, the percentage of affected individuals who died. This information is usually available in only a small proportion of cases. Thus, when calculating percentages to estimate severity, only cases for which information on death was available were included (see Table 3 for details). This is more robust than calculating percentages over all the reported cases, because in the absence of information it cannot be assumed that patients were not hospitalised or that illness did not result in death. The numbers of cases of hospitalisations and deaths (reported in square brackets) are different; some MS report whether or not a case has resulted in hospitalisation and in others (more often) report whether or not it resulted in death; case numbers with regard to hospitalisation and death were analysed independently.

The cases reported represent only the 'tip of the iceberg' of real cases: many infections are asymptomatic or cause only mild symptoms that do not result in a visit to the doctor. Furthermore, some people with severe infections do not visit the doctor. The surveillance systems are set up differently in the various EU MSs, with different case definitions, national or restricted coverage, voluntary or compulsory reporting, different focus, target group, etc.; additionally, only a small fraction of infected humans are sampled and the causal organism typed and reported to the national health institutes. Because of the above caveats, the incidence and severity figures quoted here are only approximate and must be considered with caution.

Additionally, DALY estimates for the Netherlands for 2009 were available and used as an alternative or additional indicator for disease severity, as presented in Table 4. The DALY metric encompasses the impact of mortality as well as morbidity, and is based on estimates of the true incidence of acute disease as well as sequelae. The disease burden per case therefore represents a more comprehensive measure of disease severity than reported hospitalisations and deaths. DALY data are currently available only for the Netherlands and cannot be directly extrapolated to the whole EU situation. Still, many parameters that contribute to the disease burden per case are not country specific, supporting the use of the Dutch results in an EU setting. Other important parameters that may affect the DALY estimates may include the health care system or other factors that are specific to individual MSs. ECDC has initiated the 'Burden of Communicable Diseases in Europe (BCoDE)' project, which aims to estimate the burden of communicable diseases, including food- and waterborne diseases, applying the DALY metric.[8]

8 Further information available from: http://www.ecdc.europa.eu/en/healthtopics/burden_of_communicable_diseases/project/Pages/project.aspx

Table 4: Available DALY estimates for 2009 in the Netherlands (Havelaar et al., 2012) for the identified biological hazards.

Selected hazard	DALYs per 1 000 cases (the Netherlands)
Campylobacter spp. (thermophilic)	41
VTEC (O157)	143
Salmonella spp.	49
Toxoplasma gondii (acquired/congenital)	3 170/6 360

Based on the situation in the Netherlands in 2009, *Campylobacter* spp. and *Salmonella* spp. cause a burden of 40-50 DALYs per 1 000 cases. The greater severity of diarrheal illness associated with VTEC O157 and in particular the impact of haemolytic uremic syndrome as sequelae is reflected in an approximately threefold higher burden per 1 000 cases. The burden of toxoplasmosis (in particular congenital but also acquired toxoplasmosis) is 10-100 fold higher than the burden of the other hazards. This is related to the impact of foetal and neonatal deaths, as well as the long-term impact of lesions in the eye (chorioretinitis).

2.2.2.2. Carcass prevalence data in the EU

These data represent prevalence of hazards on bovine carcasses and/or bovine meat collected within slaughterhouses. The data, supplied by EFSA, are reported to EFSA by the EU MSs and some non-MSs under the 2003/99/EC Directive.

In Table 5, data described as originating from suspect or selective sampling and from clinical investigations are excluded because they do not, in most cases, represent the actual epidemiologic situation. Food samples described as collected for HACCP and own-check purposes were excluded because the sampling scheme may be biased. Samples included are described as originating from control and eradication plans, monitoring and surveillance, and consequently they are supposed to represent the occurrence of the zoonotic agent in the reporting country over the years based on objective sampling. Monitoring and surveillance schemes for most zoonotic agents, especially for early years of reporting, are not fully harmonised between MSs. Further, in the reporting country data may not necessarily be derived from sampling plans that are statistically valid and may not accurately represent the national situation regarding the zoonoses.

Table 5: Available prevalence estimates for the period 2008–2011 for the different hazards in fresh bovine meat in the EU as reported in the EU summary report and extracted from the database on 15 April 2013. Data include the maximum and minimum reported values from a MS in a single year. The data reported are at slaughterhouse level, no stage was reported (i.e. pre or post chill), and are for single sample testing (i.e. excludes batch testing).

Hazard	Number of MSs reporting	Number of samples[1]	Average prevalence (%) (min–max)
Campylobacter spp. (thermophilic)	4	482	3.9 (0–38.5)
Salmonella spp.	12 + Norway	91 956	0.2 (0–8.0)
VTEC[2]	7	4 609	2.3 (0–14.9)
VTEC (O157)	7	4 609	1.9 (0–14.5)
Taenia saginata cysticerci	3	2 701 876	0.17 (0–0.29)

[1] Excluded are data from HACCP, own checks, clinical investigations and suspect sampling. Samples taken in slaughterhouse but no stage reported. Includes swabs (cm^2) and meat (g). All sample sizes are included.
[2] From the data provided it is not possible to determine whether or not the strains are pathogenic to humans.

At present, there is no harmonised EU monitoring system for bovine animals or bovine meat for the hazards present in the short list. Moreover, to date no EU-wide baseline surveys have been carried out addressing those hazards.

Live animal prevalence data are presented in Section 2.2.3.2 when considered necessary (e.g. to compare with and/or support carcass prevalence data) for the assessment of the hazards from the short list.

2.2.2.3. Data from other sources

The results of source attribution estimates of human cases of those hazards related to consumption of bovine meat are presented in Table 6. Overall, no source-attribution estimates are available at EU-wide level. Instead, results of country-specific estimates based on published literature are presented (Mead et al., 1999; Hoffmann et al., 2007; Havelaar et al., 2008).

Table 6: Available source attribution estimates in different countries for human cases of the relevant hazards due to consumption of bovine meat (or due to the bovine reservoir, when microbial subtyping methods were applied) based on available scientific literature and reports. The less reliable attribution estimate according to the authors is shown in square brackets.

Hazard	Geographical location	Method of attribution	Proportion of cases caused by bovine meat (%)
Campylobacter spp. (thermophilic)	Denmark	Microbial subtyping[1]	7–25 or 7–28 (depending on microbial subtyping attribution methodology)
	The Netherlands	Expert elicitation[2]	2
	United States of America (USA)	Outbreaks[3]	[5]
		Expert elicitation[3]	3
	Canada	Expert elicitation[4]	5
Salmonella spp.	Denmark	Microbial subtyping[1]	6
	The Netherlands	Microbial subtyping[5]	16 (including data from clinically suspect cattle)
		Expert elicitation[2]	7
	USA	Expert elicitation	10
		Outbreaks[6]	7
	Canada	Expert elicitation[4]	5
Pathogenic VTEC (other than O157)	The Netherlands	Expert elicitation[2]	26
	USA	Outbreaks[3]	32
VTEC (O157)	The Netherlands	Expert elicitation[1]	18
	USA	Outbreaks[3]	38
		Outbreaks[6]	27
		Expert elicitation[3]	[58]
	Canada	Expert elicitation[4]	41
Sarcocystis hominis	NA[7]	NA	Transmitted only by bovine meat
Taenia saginata	NA	NA	Transmitted only by bovine meat
Toxoplasma gondii	The Netherlands	Expert elicitation[2]	13
	USA	Outbreaks[6]	0
		Expert elicitation[3]	12

[1] Attribution to cattle reservoir, not specifically to beef. Based on Annual Report of Zoonoses in Denmark 2011 (DTU, 2012a).
[2] Based on Havelaar et al. (2008).

[3] Outbreak estimates for the USA are based on Batz et al. (Batz et al., 2012). These authors compared expert elicitation estimates as published by Hoffmann et al. (2007) with outbreak based attribution, using the food categorisation scheme proposed by Painter et al. (Painter et al., 2009). They conclude that for *Salmonella* spp. and VTEC, outbreaks provide the strongest information for attribution, whereas for other pathogens, expert elicitation provides the most robust information. The attribution based on outbreak data has been calculated by multiplying the fraction of food-borne cases attributed to beef as presented by Batz et al. (Batz et al., 2012), with the fraction of all cases that is food-borne as presented by Scallan et al. (Scallan et al., 2011)

[4] Data for Canada are based on two expert elicitation surveys (Ravel et al., 2010; Davidson et al., 2011). Ravel and colleagues report on the proportion of gastrointestinal illness that is food-borne. The authors found diverging opinions between experts and break down their results in two groups of experts. In a second paper authored by Davidson and colleagues, which describe attribution to food groups, the authors conclude that the group of experts who estimate higher percentages food-borne are "more consistent with comparison data", and use these estimates in their further analysis. We follow this choice and multiply the proportion food-borne in Ravel and colleagues with the proportion of food-borne cases attributed to beef in Davidson and colleagues.

[5] Attribution to cattle reservoir, no specifically to beef. Based on Maassen et al. (2012).

[6] A second (more recent) source for attribution based on US outbreak data from Painter et al. (2013).

[7] NA = not applicable.

Apart from these data, and where needed, other further hazard-specific data are presented and discussed when addressing the individual hazards from the short list in Section 2.2.3.2.

2.2.3. Results of the priority ranking

2.2.3.1. Bovine meat-associated hazards excluded because their risk is related to growth or introduction on carcasses or meat at post-chill steps

After the first step of the risk ranking process (Figure 1), the following hazards were not considered further:

- *L. monocytogenes* and toxins of *B. cereus*, *C. botulinum*, *C. perfringens* and *S. aureus*

All these are considered as hazards for which the public health risk is mainly controlled after carcass chilling. Specifically, *B. cereus*, *C. botulinum*[9] (proteolytic types that may be found in bovine meat), *C. perfringens* and *S. aureus* are considered to be ubiquitous bacteria and can be found in a variety of foods as well as in the environment. In the case of *S. aureus*, human-to-human transmission seems also to be important. However, spores for germinating (i.e. *B. cereus*, *C. botulinum*, *C. perfringens*) and their vegetative forms need temperatures above those used for refrigeration to grow to levels of concentration of public health relevance, and thus the risk of disease seems to be related not to occurrence in carcass meat but rather to improper hygiene and storage of foods. Illness caused by *L. monocytogenes*, which is also a ubiquitous bacterium, is usually associated with ready-to-eat products (including processed foods). Initial contamination with *L. monocytogenes* is eliminated by application of a bactericidal step, but the organism may then be re-introduced post processing (e.g. during slicing, packaging), and is followed by growth during prolonged storage, even at refrigeration temperatures.

[9] *C. botulinum* Type E, usually associated with fish, can grow at 3 ^{o}C.

2.2.3.2. Priority ranking of relevant bovine meat biological hazards present on carcasses at post-chill

Bacillus anthracis

- **Human incidence:** based on EU data, 'Low'

  The reported notification rate of anthrax in humans in the EU in 2011 was below 0.01 cases per 100 000 adult population. Between 2008 and 2011 the number of cases reported to ECDC ranged from two confirmed cases (2008) to 32 cases (2010) (see Table 3 above).

- **Severity of disease:** based on EU data, 'High'

  In the EU, the percentage of reported deaths among confirmed cases in 2010 and 2011 was 38 % and 25 %, respectively.

- **Evidence for meat from bovine animals as an important risk factor:** based on the evidence available and discussed below, 'No'

  Epidemiological link. *Bacillus anthracis* has a worldwide distribution, persisting in the soil in the form of extremely resistant spores for many years. If the vegetative form or its spores are inhaled, contacted with or are ingested it causes a highly infectious notifiable disease in farm and wild animals (Swartz, 2001). The disease is endemic in most countries in Africa and Asia (Thurnbull, 1998) and in defined regions of other countries. In cattle the disease usually causes peracute or acute septicaemic and is rapidly fatal, with death occurring in some cases within hours. Affected animals show multiple haemorrhages from natural orifices and, although most are found dead without showing premonitory signs, pyrexia with temperatures up to 42 °C along with depression, congested mucosae and petechiae may be observed *ante-mortem*. In cattle, *post-mortem* findings are characterised by incomplete rigor mortis, widespread ecchymotic haemorrhages and oedema, dark, unclotted blood and blood-stained fluid in body cavities and severe splenomegaly (Quinn et al., 2002). Direct contact with such animals and carcasses is highly dangerous.

  Human cases of pulmonary anthrax have been linked to the large-scale processing of hides and wool in enclosed factory spaces, where aerosolised anthrax spores may be inhaled. Humans also acquire the cutaneous form of anthrax from handling contaminated animal products, such as hides, wool and hair. Cases of gastrointestinal anthrax have resulted from the ingestion of raw or undercooked meat (CFSPH, 2005) or of well-cooked beef from infected animals (CDC, 2000).

  Human anthrax persists in Russia, perhaps for the following reasons (Halat, 2011): (1) uncontrolled slaughtering of sick livestock without prior veterinary examination and laboratory testing; (2) the distribution of meat and by-products from such dead and slaughtered sick animals through the trading networks and the food industry; (3) increase in the uncontrolled use of wool and hides from dead and slaughtered sick animals; (4) increase in the numbers of cases related to the importation of infected meat and other animal products form other states of the Commonwealth of Independent States (CIS); (5) decrease in anthrax vaccination of high-risk livestock; and (6) poor awareness of anthrax and proper prophylactic methods.

  Consumption of meat (including bovine meat) from carcasses of animals showing clinical signs of anthrax, or which have died from the disease, is the most commonly reported route of

food-borne infection resulting in gastrointestinal anthrax. In the EU, none of the TESSy cases were reported to be linked to consumption of bovine meat. Indeed, bovine meat-borne transmission of anthrax in the EU has been a very rare event, if reported at all. Recently, a case of anthrax *possibly* acquired through handling or consumption of contaminated beef in a household was reported in Romania (Popescu et al., 2011).

Carcass/Animal prevalence. Reported outbreaks of anthrax in animals including cattle in the EU can be found in the World Animal Health WAHID database (OIE, 2013). The number of reported anthrax outbreaks in cattle herds in the EU during the period 2007-2011 ranged from 6 to 25 yearly. As an example, an outbreak of anthrax was reported among cattle, sheep and horses in Italy in 2011.

Overall, the number of outbreaks in farm animals is nowadays much lower than in the 1970s and 1980s, when the annual number of outbreaks was around 10-30 times higher than in recent years (Velimerovic, 1984). Anthrax is now rare in livestock in the EU, and the major enzootic areas are Greece, Spain, France and Italy (Fouet et al., 2002; Fasanella et al., 2005; OIE, 2013). Data on occurrence of spores of *B. anthracis* in carcasses of bovine animals slaughtered for human consumption are not available as it is not a pathogen commonly tested for.

Expert Opinion that bovine meat consumption is an important risk factor Based on the information and data presented above, expert opinion concludes that bovine meat can be regarded as not being an important risk factor.

Therefore, based on the data available and on the considerations presented above the priority ranking for *B. anthracis* is assessed to be '**Low**'. This result is not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures). Therefore, *B. anthracis* is not considered further in this Opinion.

***Campylobacter* spp. (thermophilic)**

- **Human incidence:** based on EU TESSy data, 'High'

  Campylobacteriosis is the most frequently reported zoonotic illness in the EU, with 215 801 confirmed cases being reported in 2011, a notification rate of 71.53 per 100 000 population (based on TESSY data; Table 3). However, it is estimated that the true incidence is 9 million cases of illness annually in the EU-27 (EFSA Panel on Biological Hazards, 2011b).

- **Severity of disease**: According to the decision tree (Figure 1), when the incidence is high, the severity does not need to be considered.

- **Evidence for meat from bovine animals as an important risk factor:** Based on the evidence available and discussed below, 'No'.

  ***Epidemiological link*.** Source-attribution studies of human campylobacteriosis are presented in Table 6.

  Epidemiological studies have consistently confirmed that the main route for campylobacteriosis is the handling, preparation and/or consumption of poultry (EFSA Panel on Biological Hazards, 2010; Perez-Perez and Kienesberger, 2013). This is not unexpected as a high proportion of chickens are contaminated with *C. jejuni* and *C. coli* (EFSA Panel on Biological Hazards, 2011b). Handling, preparation and consumption of broiler meat is estimated to account for 20-30 % of human cases of campylobacteriosis, while 50-80 % may be attributed to the chicken reservoir as a whole (EFSA Panel on Biological Hazards, 2010a).

As the majority of cases are sporadic the true origin is rarely identified and many foods, including red meats, are considered potential sources of *C. jejuni*.

Campylobacter outbreaks associated with beef or other bovine meat and products thereof have rarely been reported in the EU. Between 2007 and 2009, of the 67 verified outbreaks, only three were linked to the consumption of bovine meat or bovine meat products. During the years 2010 and 2011, out of the 64 strong evidence outbreaks reported, one was linked to the consumption of bovine meat or bovine meat products. Pires and colleagues (2010) did not identify beef as a source of *Campylobacter* infection in humans based on outbreak data for source attribution of human salmonellosis and campylobacteriosis cases in Europe.

Outbreak derived attribution based on data obtained in the USA between 1999 and 2008 suggests that 7/120 (5.8 %) of *Campylobacter* outbreaks during this period were associated with beef (Batz et al., 2012). The epidemiological approach has major disadvantages including investigation, detection, reporting and publication bias as well as geographical inconsistency (O'Brien et al., 2006). This uncertainty is illustrated by the Batz study, in which the food source attribution for beef decreased from 5.8 % to 4.4 % when expert elicitation was included in the analysis. Greig and Ravel (Greig and Ravel, 2009) suggested that a similar percentage (4.7 %) of campylobacteriosis outbreaks (including in the EU) between 1988 and 2007 were associated with beef. However, the total number of *Campylobacter* infections in the EU attributable to beef cannot be estimated simply by multiplying this figure by the number of confirmed cases reported annually by ECDC and EFSA, as the vast majority of the cases are sporadic and with no source attribution information. As the majority of campylobacteriosis cases are sporadic and with no confirmed source attribution, the validity of relying on the limited outbreak data for priority ranking is questionable.

A recent systematic review (Domingues et al., 2012a) on source attribution of human campylobacteriosis using a meta-analysis of case-control studies of sporadic infections, found that travelling abroad, eating undercooked chicken and direct contact with environmental sources and farm animals were significant risk factors for campylobacteriosis. In the same study, results of a sub-analysis by location showed that consumption of beef in restaurants was a risk factor, but eating beef or pork at home was not determined as important for infection. Only a small number of studies (n=3) included in the systematic review focused on eating pork or beef in a restaurant, and thus the impact of different locations was not confirmed. Overall, in this publication, the odds ratio (OR) for beef as a risk factor for sporadic campylobacteriosis cases was 0.87 (95 % C.I.=0.70-1.09), while for poultry it was 1.28 (95 % C.I.=1.01-1.62), for pork 1.03 (95 % C.I.=0.73-1.45), and for lamb 0.73 (95 % CI=0.50-1.06).

Studies (University of Aberdeen, 2009) have investigated the molecular epidemiology of *Campylobacter* isolates in Scotland from human cases employing Multilocus Sequence Typing (MLST). In these studies approximately three-quarters of human clinical isolates could be attributed to six potential reservoirs of infection: less than 1 % could be attributed to pigs, 5-6 % to wild birds, 12-15 % each to cattle, sheep and companion animals (if cats and dogs excluded, 15-18 % each to cattle and sheep), and just over 30 % to retail chicken. The study identified farm ruminants (i.e. bovine animals and ovine animals) as reservoirs, but for which the infection routes for humans were uncertain.

A recent re-analysis of a case-control study in the Netherlands investigated risk factors separately for *Campylobacter* strains (both *C. jejuni* and *C. coli*) *of* chicken, ruminant and environmental origin (MLST) (Mughini Gras et al., 2012). From these studies 20.7 % of the human cases were deemed to be associated with the cattle reservoir, and 2.5 % with the sheep reservoir. Beef was not a significant risk factor in the overall dataset, and was a protective factor for strains of chicken origin. Among ruminant strains, food-related risk factors were consumption tripe (population attributable risk (PAR) of 12 %) and consumption of

barbecued, grilled or microwaved (unspecified) meat (PAR 63 %). As ruminant strains represented 23.2 % of all human strains, the PAR for tripe consumption at population level was 2.8 %.

In Denmark, the sources of 297 human cases of domestic campylobacteriosis in 2011 were estimated using two models (the CAMSA model or the Island model) (DTU, 2012a). The proportion of cases that could be attributed to the cattle reservoir was 7 % to 25 % (based on the CAMSA model, between 10 % to 31 % classified as unknown) and 7 % to 28 % (based on the Island model, 0 % classified as unknown). The authors found a high prevalence of *C. jejuni* in cattle, but a low occurrence in Danish beef, thus highlighting the need to consider other non-meat-borne transmission routes for the cattle origin.

Further studies of source attribution estimates based on expert elicitation (Table 6) estimate bovine meat as the source for between 2 % and 5.8 % of human campylobacteriosis cases. The CIs of the estimates of the studies based on expert elicitation do not exclude 0 %.

Carcass/Animal prevalence. Between 2008 and 2011, the average prevalence in the EU of *Campylobacter* in meat samples at slaughterhouse has been reported to be 3.9 % (Table 5). The number of MSs reporting is very small (four). It is important to note that detailed information on the sampling stage at the slaughterhouse (i.e. pre- or post-carcass chilling) is not available. *Campylobacter* cells are sensitive to the desiccation that occurs as beef carcass surfaces dry during chilling (Wallace, 2003; Lake et al., 2007). This may explain why bovine meat does not appear to be an important source of campylobacteriosis outbreaks.

According to scientific literature, bovine animals are frequently (up to 80 %) colonised with *Campylobacter* spp. (in particular *C. jejuni*) (Stanley et al., 1998). From 2004 to 2009 fresh beef contamination rates at slaughter ranged from 0 to 11.9 % in the EU (DTU, 2012b). A recent study, conducted in Ireland and Poland, reported up to 16 % of carcasses contaminated with *Campylobacter* pre-chill but the organism was not detected post chilling (ProSafeBeef, 2012). On the other hand, it should not be ignored that studies have demonstrated an enhanced ability for *Campylobacter* to survive under chilled conditions in vacuum packages, when drying will not occur, such as in the case of hot boning and immediate packaging (Balamurugan et al., 2001; Dykes and Moorhead, 2001). As such meat handling and packaging technologies become more widely used in the beef industry, the risk of beef associated *Campylobacter* infections may increase in the future. Furthermore, edible offal such as bovine livers may harbour *Campylobacter*, and the possibility of consumers acquiring infection from undercooked livers cannot be discounted (Enokimoto et al., 2007; Kramer et al., 2000).

Expert Opinion that bovine meat consumption is a risk factor. There is uncertainty about the extent to which bovine meat contributes to human campylobacteriosis owing to data gaps. There are a small number of confirmed outbreaks in the EU, and case-control studies based on sporadic cases do not identify consumption of bovine meat as an important risk factor. Source attribution estimates based on microbial subtyping methods do not exclude the overall importance of the bovine reservoir, however pathways other than meat must also be considered. Thus, unequivocal priority ranking is difficult. Based on the data available, the bovine animal reservoir could not be excluded as an important source of human campylobacteriosis, but the importance of the meat-borne route originating from chilled carcasses is considered to be low, in particular because of the effect of carcass chilling on the survival of *Campylobacter* spp. (thermophilic).

Based on the data available and on the considerations presented above the priority ranking for *Campylobacter* spp. (thermophilic) is currently assessed to be **'Low'**. This current ranking is not the result of current controls (i.e. any hazard-specific control measures implemented at farm and/or

slaughter level before chilling of the carcasses, including current meat inspection procedures). Nevertheless, the effect of carcass chilling in the potentially reduced survival of *Campylobacter* spp. (thermophilic) as a non-hazard-specific control measure has to be taken into account. Therefore *Campylobacter* spp. (thermophilic) is not considered further in this Opinion.

Campylobacter remains a very important cause of human infection and since, because data gaps, there is uncertainty in the extent to which bovine meat contributes to human campylobacteriosis, new information should be carefully monitored as it becomes available.

Pathogenic VTEC

VTEC are characterised by the production of verocytotoxins, so called because of their activity on Vero cells, but also referred to as shiga toxins, because of their similarity with the toxin produced by *Shigella dysenteriae*. Not all VTEC strains have been associated with human disease and there is no single or combination of marker(s) that defines a 'pathogenic' VTEC (EFSA Panel on Biological Hazards, 2013). While *stx*2- and *eae*- positive strains are associated with a high risk of more serious illness, other virulence gene combinations and/or serotypes may also be associated with serious disease in humans, including haemolytic uremic syndrome (HUS). Patient-associated factors such as age, immune status, antibiotic therapy, etc. also influence the likelihood and severity of disease. VTEC considered to be relevant hazards in the context of this opinion are therefore referred to as 'pathogenic VTEC'.

In Europe approximately half of all confirmed VTEC cases are associated with serogroup O157. Of the non-O157 cases, O26, O103, O145, O111, and O91 have also been isolated from patients. In 2011, *E. coli* O104:H4 caused a major outbreak which resulted in 4 321 confirmed cases, including 852 cases of HUS, with 54 deaths reported in 14 EU MSs, the USA and Canada when the epidemic was declared to be over at the end of July 2011 (Karch et al., 2012).

- **Human incidence:** Based on EU TESSy data, 'Low'

  Based on TESSY data (see Table 3), the notification rate of VTEC in the EU in 2011 was 2.56 cases per 100 000 population. For serogroup O157, the notification rate for the same year was of 0.45 cases per 100 000 population.

  Many cases are not recorded by the notification or surveillance system because healthcare advice is not always sought. This is referred to as 'under-ascertainment'. Under-reporting (cases where healthcare advice is sought but the infection status is misdiagnosed, misclassified, miscounted or the information is not reported in detail) is also an issue. The incidences of VTEC cases cannot therefore be calculated on the basis of historical data alone but requires a 'disease-multiplier' (a hazard-specific value that expresses the degree of under-reporting and under-ascertainment). In Europe the disease multipliers for O157 and non-O157 VTEC are estimated to be 51.2 and 209.6, respectively (EFSA Panel on Biological Hazards, 2013). Using those multipliers, the average number of confirmed cases of O157 and non-O157 in the EU per annum between 2007 and 2010 were estimated to have been 85 222 and 149 445, respectively.

  The rate of reported confirmed VTEC cases in the EU has followed a steadily increasing trend since 2008. This was based on data received from 25 EU MSs and two EEA/EFTA countries that reported consistently during the period 2008-2010 (ECDC, 2011; EFSA and ECDC, 2013). In 2009, for instance, the highest rate of confirmed cases was reported in 0–4 year-old males (6.98 cases per 100 000 population) followed by 0-4 year old females (5.82 cases per 100 000 population). Notification rates were remarkably lower in older age groups. Young children are more likely than persons in other age groups to be brought in for medical attention for diarrhoeal illness, but this is just part of the explanation. Another is that the immune system in young children is not fully developed.

The increase in the number of reported cases in 2011 compared to 2010 (over 150 % increase) was due to the outbreak caused by VTEC O104:H4 that occurred in Germany and took international dimension (including non EU MSs) (Karch et al., 2012; EFSA and ECDC, 2013).

- **Severity of disease:** based on EU TESSy data, 'High'

  As shown in Table 3, the percentage of reported deaths among confirmed cases of VTEC in the EU were 0.38 % and 0.75 % in 2010 and 2011, respectively. Regarding the particular serogroup O157, the percentages were higher for the same years: 0.56 % and 0.36 %, respectively.

  More than half (52 %) of reported confirmed VTEC infections in 2009 were associated with the O157 serogroup, and a total of 242 individuals with confirmed VTEC infection developed HUS. This represents an increase of 66 % compared with the number of HUS cases reported in 2008. Sixty-three per cent of HUS cases (n=153) were reported in children aged 0–4 years.

  Based on the situation in the Netherlands in 2009, severity of diarrheal illness associated with VTEC O157 and in particular the impact of haemolytic uremic syndrome as sequelae is 143 DALYs per 1 000 cases.

- **Evidence for meat from bovine animals as an important risk factor:** based on the evidence available and discussed below, 'Yes'

  ***Epidemiological link*.** Since the first confirmed case in 1982, beef associated VTEC-O157 outbreaks have been widely reported (Currie et al., 2007; Ethelberg et al., 2009; King et al., 2009; Riley et al., 1983). Between 2007 and 2009, of the 57 verified food-borne outbreaks of VTEC, eight were linked to the consumption of bovine meat or bovine meat products. During the years 2010 and 2011, out of the 16 strong evidence outbreaks reported, two were linked to the consumption of bovine meat or bovine meat products. In 2011, 12 MSs reported a total of 60 food-borne outbreaks caused by VTEC, which was 1.1 % of the total number of reported food-borne outbreaks in the EU. Fourteen VTEC outbreaks (28.0 %) were supported by strong evidence and two of them were linked to bovine meat or products thereof (EFSA Panel on Biological Hazards, 2013).

  Studies in young children have identified various food and non-food exposures - such as visiting petting farms/petting zoos, riding in a shopping cart near raw meat, and contact with baby chicks, turtles, and water frogs - that also can increase the risk of infection with the pathogen (Heuvelink et al., 2002). Further studies which provide source-attribution estimates, as presented above in Table 6, identify bovine meat as the source for between 26 % and 32 % of human cases.

  Carcass/animal prevalence. Cattle and to a lesser extent other ruminant animals are the primary reservoir of VTEC (Caprioli et al., 2005). The prevalence of VTEC O157 in European cattle reportedly ranges from 0 % to 5 % (Bolton et al., 2009). The official monitoring data collected under Directive 2003/99/EC for 2007-2010 suggest that 0-17 % of cattle carried VTEC O157 (EFSA and ECDC, 2012a). Cattle are also considered the primary source of most non-O157 VTEC cases (Bosilevac and Koohmaraie, 2011). In recent years confirmed cases of non-O157 infection in the human population have equalled or surpassed those caused by serogroup O157 in Europe (EFSA and ECDC, 2012a).

  Published data suggest data the prevalence of non-O157 on beef carcasses rates ranges from less than 2 % to 54 % (Arthur et al., 2002; Leung et al., 2001; Monaghan et al., 2012; Rigobelo et al., 2006; Rogerie et al., 2001). Between 2008 and 2011, 0 % to 14.9 % of fresh

bovine meat samples taken at slaughterhouse level tested positive for VTEC in the reporting MSs (Table 5), and 0 % to 14.5 % of these samples were positive for VTEC O157. As laboratories in most MSs do not test for non-O157 strains, there are limited data for these serogroups. In 2010, the proportion of positive samples varied from 0 % to 14.9 % among testing MSs. In 2011, the proportion of non-O157 reported in the EU varied between 0 % and 3.8% . Serogroups O26 and O145 were detected in bovine meat in France in 2010, and O26, O103, O111 and O145 in Belgium in 2011 (EFSA and ECDC, 2012a, 2013).

VTEC O157 colonise the gastrointestinal tract with high concentrations found in the terminal rectum. Although the majority of animals within any given herd may carry VTEC O157, shedding is intermittent and at any one time faeces samples from a relatively few animals are contaminated. Several studies have observed so called 'super-shedding' in some animals, defined as the shedding of high concentrations of up to 10^8 VTEC organisms per gram of faeces (Besser et al., 2001; Fukushima and Seki, 2004) are shed by certain animals (Naylor et al., 2005). Low level shedding may be the result of environmental exposure with no shedding while super shedding (defined as $>10^3$ colony-forming units (CFU/g)) is the result of colonisation. In either case, super-shedders are considered to be responsible for over 95 % of the *E. coli* O157 shed by cattle (Naylor et al., 2005) and have a significant impact on on-farm epidemiology and beef carcass contamination (Karmali et al., 2010).

A recent Irish study screened 450 beef animal hides and a similar number of carcasses for VTEC in three beef slaughterhouses over a 12 month period, using polymerase chain reaction (PCR) and culture-based methods. The results indicated that 67 % (301/450) of hides and 27% (122/450) of carcasses were VTEC positive by PCR. The corresponding figures using culture-based methods were 5.6 % and 1.1 %, respectively (Monaghan et al., 2012).

The majority of veal calves in Europe are produced in Italy, France and the Netherlands (Sans and de Fontguyon, 2009). Rearing systems are similar in these countries. Calves, typically two weeks old are raised in specialised fattening units under intensive rearing conditions. White veal is a product of a low supply of dietary iron. In contrast, calves used to produce pink or rose veal have no iron restriction. White veal calves are fed a diet that consists mainly of milk replacer with a modest supplement of roughage and/or concentrates.

Pink veal production herds have a higher incidence of VTEC carriage than their white veal equivalents (31.3 % vs 2.6 %, (Schouten et al., 2005). Berends and colleagues (2008) also reported a large difference in VTEC O157 prevalence in pink (39.8 %) and white (1.5 %) veal herds. This may be attributed to a combination of age and diet. This study also reported that pink veal calves tested VTEC-positive within a short time after they are housed in the herd while white veal remained negative for up to four months, suggesting that reduced biosecurity and cross-contamination from older animals was an important risk factor.

Expert Opinion that bovine meat consumption is an important risk factor. Based on the information and data presented above, expert opinion concludes that consumption of bovine meat can be regarded as an important risk factor for pathogenic VTEC.

Therefore, based on the data available and on the considerations presented above the priority ranking for pathogenic VTEC is assessed to be '**High**'.

ESBL/AmpC gene-carrying bacteria

ESBLs are defined as plasmid-encoded enzymes found in *Enterobacteriaceae* that confer resistance to a variety of Beta(β)-lactam antimicrobials, including penicillins, second-, third- and fourth-generation cephalosporins, and monobactams (EFSA Panel on Biological Hazards, 2011a).

Although ESBL genes may be carried by a wide variety of *Enterobacteriaeceae*, most data are available on *E. coli*. Furthermore, based on indirect evidence, as explained below and as previously assessed by EFSA (EFSA Panel on Biological Hazards, 2011a), ESBL/AmpC *E. coli* are implicated as also being potentially transmitted by food. Therefore, this evaluation focuses on ESBL/AmpC gene-carrying *E. coli*.

E. coli (both strains with the potential to cause human disease and also non-pathogenic commensal strains) may develop resistance to third-generation cephalosporins such as cefotaxime by several different mechanisms, the most common of which is the acquisition, primarily by conjugation, of plasmid-mediated β–lactamase genes. *E. coli* may also possess an endogenous AmpC β–lactamase which, when activated, confers resistance to third-generation cephalosporins. The occurrence of ESBL/AmpC-producing *E. coli* in food-producing animals is a possible consequence of the veterinary use of third-generation cephalosporins is such animals. Because of the plasmid-mediated nature of ESBL/AmpC resistance, the application of other unrelated antimicrobials may also contribute to the acquisition of ESBL/AmpC genes, particularly if resistance to such antimicrobials is encoded on the same plasmid(s) as the ESBL/AmpC resistance genes.

- **Human incidence:** no relevant EU-wide data available; 'Unclear' based on other available data.

  There are no relevant TESSy EU wide data available on ESBL/AmpC gene-carrying *E. coli* in humans. Some reporting activity was done in 2011, where isolates from 118 cases were tested, of which 0.03 % were positive. This result is considered as anecdotical as so few samples cannot be regarded as fully representative of the overall EU situation.

  European Antibiotic Resistance Surveillance (EARS-Net)[10] data are laboratory retrieved data referring to invasive bacterial isolates (for *E. coli* and some others) found in blood and cerebrospinal fluid (CSF) of humans. Data are collected for the purpose of surveillance of antimicrobial resistance trends in invasive bacteria. The Antimicrobial Resistance Surveillance in Europe 2011 Report (ECDC, 2012) states that between 2005 and 2011, of 344 700 isolates of *E. coli* recorded in the EARS database, 6.7 % were resistant to 3rd- generation cephalosporins; 70 % of such isolates came from inpatients, and 7.1 % of these were resistant to third-generation cephalosporins. For 2011, the figures were as follows: 29 countries reported 61 544 *E. coli* isolates, of which 5 619 (9.1 %) were resistant to third-generation cephalosporins. Fourteen of 17 countries reported between 85 % and 100 % ESBL-positive isolates among isolates resistant to third-generation cephalosporins. Resistance to third-generation cephalosporins can be used as an indicator for ESBL positivity. For the period 2008–2011 a significant increase in third-generation cephalosporin resistance in such isolates was observed in 18 European countries, with none of the data from reporting countries indicating a decreasing trend.

  EARS-Net data cannot be used to asses the incidence of ESBL/AmpC-producing *E. coli* in humans in the EU. Such data are retrieved only from bacterial isolates from blood and CSF, and are not linked specifically to human cases. Furthermore, any possible food origin of such isolates is not known.

  Studies have reported the rate of faecal carriage of ESBL/AmpC-producing *Enterobacteriaceae* to be between 3.7 and 5.5 % in non-hospitalised patients in Spain (Valverde et al., 2004), and 10.8 % in patients admitted to a hospital in Tel Aviv (Ben-Ami et al., 2006). In the later study, 14 % of bloodstream infections in non-hospitalised patients were also caused by *Enterobacteriaceae* resistant to third-generation cephalosporins. A further study (Rodriguez-Bano et al., 2008) states that the estimated population-based incidence of

[10] More details can be found at: http://ecdc.europa.eu/en/publications/Publications/Forms/ECDC_DispForm.aspx?ID=998.

community acquired infection due to ESBL-producing bacteria in Spain was 2.2 cases per 100 000 population per year.

- **Severity of disease:** no relevant EU-wide data available; 'Unclear' based on other available data.

  The limitation of EARS Net data for severity estimates are similar to those that apply when estimating incidence. Thus, individual studies in scientific literature and reports may be used as an alternative source of information.

  In 2012, the BIOHAZ Panel concluded that the severity of ESBL-producing *E. coli* infections was high, based on expert opinion on reported excess mortality (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012). This Opinion is supported by a recent meta-analysis in the Netherlands of health-care associated infections with ESBL-producing organisms, which concluded that the pooled OR for the unadjusted mortality associated with ESBL production was 2.35 (95 % C.I.: 1.90-2.91) and the adjusted OR was 1.52 (Rottier et al., 2012). In contrast, a multi-centre study has concluded that there was no significant effect of inadequate empirical therapy on 30-day survival of patients with bloodstream infections with ESBL-producing organisms (Frakking et al., 2013). Underlying illness, severe sepsis and the age of the patient were considered more important predictors of mortality. Thus, following on from these two studies, there is a degree of uncertainty in this area since excess mortality is probably multifactoral.

- **Evidence for meat from bovine animals as an important risk factor:** based on the evidence available and discussed below, 'Unclear'

  ***Epidemiological link*.** There is no evidence for the transfer of ESBL/AmpC-producing *E. coli* from the bovine animal production reservoir to humans. Nevertheless the possibility of such transfer cannot be discounted, as a number of studies have demonstrated that the same ESBL encoding genes, mobile genetic elements and plasmids have been found in isolates from cattle and humans (Lavilla et al., 2008; EFSA Panel on Biological Hazards, 2011a). The epidemiology of ESBL/AmpC gene-carrying bacteria and/or genes is complex. The genes themselves are transferable within bacteria by several methods, and the demonstration of identical genes in human and cattle isolates is not sufficient to draw conclusions on the routes of transmission.

  Studies in the Netherlands on ESBL-producing bacteria in veal calves concluded that the prevalence and genetic diversity of ESBL/AmpC-producing *E. coli* has increased over the years 1997-2010 (Hordijk et al., 2013). Using selective pre-enrichment methodology, a 39 % prevalence of susceptibility to cefotaxime was observed at the individual animal level in 2010. Within farm-dynamics were highly complex, with indications of high initial prevalence and diversity of genes, plasmids and *E. coli* strains, possibly related to the origin of animals from multiple farms. Clonal spread of ESBL-producing bacteria was identified on some farms, and changes in the prevalence and types of ESBL genes after (group) treatment with antimicrobial agents were observed. Similarities between isolates from veal calves and humans at the level of genes, plasmids and *E. coli* types were demonstrated but no specific studies on transmission to humans were performed.

  Carcass/animal prevalence. Data on the occurrence of ESBL/AmpC-producing bacteria in bovine animals and/or bovine meat are limited. Although MSs are not required to screen *E. coli* isolates from food or food animals for cefotaxime resistance, some data are available and would suggest that a low percentage of bovine *E. coli* isolates display ESBL/AmpC- mediated resistance. Between 2007 and 2009 inclusive the percentage of *E. coli* isolates from live

bovine animals displaying resistance to cefotaxime, ceftazidime and/or ceftiofur ranged from 0.83 to 1.6 % (EFSA Panel on Biological Hazards, 2011a). Random selection procedures and low method sensitivity may have resulted in underreporting. Further information is available in the scientific literature.

Geser and colleagues (2012) examined food animals in Switzerland as a possible reservoir of ESBL-producing *Enterobacteriaceae* and found 13.7 % (17/124) of bovine faecal samples positive. Although the incidence in calves was higher (25.3%), poultry at 63.4 % showed the highest incidence. In Japan, Hiori et al. (Hiroi et al., 2012) reported similar findings for cattle (12.5 %) and poultry (60 %).

Overdevest and colleagues (2011) reported that 4.7 % (4/85) of beef samples tested in a Dutch study were contaminated with ESBL-producing *E. coli*. This is well below the occurrence of such organisms in poultry meat (79.8 %). In Denmark, between 2009 and 2011 resistant genes (CTX-M-1, CMY-2 and TEM-52) were isolated from *E. coli* isolates from Danish and imported meat but in a small number of samples (i.e. less than 1 % of in approximately 300 yearly tested beef samples) (SSI and DTU, 2012).

***Expert opinion that bovine meat consumption is a risk factor*.** In conclusion, owing to data gaps, there is uncertainty regarding the role of bovine meat in human exposure to ESBL/AmpC gene-carrying *E. coli*, and only indirect evidence of the possible food-borne transmission of ESBL/AmpC gene-carrying bacteria is available.

Based on the data available and on the considerations presented above, the priority ranking for ESBL/AmpC gene-carrying *E. coli* cannot be assessed at this time and thus it is characterised as **'Undetermined'**. Since there is uncertainty about the role of and extent to which bovine meat contributes to ESBL/AmpC resistance in humans, new information should be carefully monitored as it becomes available.

***Salmonella* spp.**

- **Human incidence:** based on EU data, 'High'

  Salmonella spp. are one of the most common and widely distributed food-borne pathogens in the EU and salmonellosis is a major cause of human bacterial enteric illness second only to campylobacteriosis. In the EU, 94 264 confirmed salmonellosis cases in humans were reported in 2011, a notification rate of 20.37 per 100 000 population (based on TESSY data, see Table 3). However, it is estimated though that the true incidence is 6 million cases of illness annually in the EU-27 (EFSA Panel on Biological Hazards, 2011c).

  The most commonly reported serovars in confirmed cases of human infection in Europe are *S.* Enteridis and *S.* Typhimurium. In 2011, these serovars accounted for 44.4 % and 24.9 % of salmonellosis cases, respectively, followed by monophasic *S.* Typhimurium (4.7 %), *S.* Infantis (2.2 %), *S.* Newport (1 %) and *S.* Derby (0.9 %) (EFSA and ECDC, 2013). *S.* Typhimurium definitive phage type (DT) 193 (DT193), common in pigs and cattle, was the most common (21 %) phage type reported in 2010 (EFSA and ECDC, 2012a).

- **Severity of disease:** According to the decision tree (Figure 1), when the human incidence is high, the severity does not need to be considered.

  Nevertheless, it is important to highlight that while most *Salmonella* serovars cause a self-limiting gastroenteritis manifested as diarrhoea, stomach cramps with occasional vomiting or fever, there is also an invasive form of infection and salmonellosis causes more deaths than campylobacteriosis.

In the EU, *S.* Enteritidis and *S.* Typhimurium are the serovars most frequently associated with human illness. Cases caused by *S.* Typhimurium are mostly associated with the consumption of contaminated pig, poultry and bovine meat. Human infection with *S.* Dublin is associated with a higher risk of invasive disease. Infection with this serovar has been reported to result in septicaemia in more than 20 % of all *Salmonella* infections in England and Wales (Threlfall et al., 1992), 40 % in the EU as a whole (Wollin, 2007) and 60 % in the USA (Jones et al., 2008), whereas septicaemia due to infection with the other serovars occurs in less than 2 % of cases in England and Wales and the EU as whole, and in about 7 % of cases in the USA. These apparent discrepancies may result from differences in health systems in the EU and the USA.

Amongst all human salmonellosis cases reported to TESSy for the period 2009 to 2011 (when data on hospitalisation was introduced), 10 % included information on whether the patient was hospitalised: this information was not available for the remaining 90 % of the cases. Where information was available, 40 % resulted in hospitalisation. In the case of infection with *S.* Dublin, 83% resulted in hospitalisation. Furthermore, the same TESSy data for the period 2007 to 2011 showed a higher proportion of systemic infections (based on the isolation of the bacterium from blood) due to *S.* Dublin as compared to all *Salmonella* spp. (46 % vs 2 %). Although undoubtedly a pathogen associated with bovine animals, several outbreaks of infection with *S.* Dublin in EU MSs and the USA have been associated with contaminated unpasteurised milk (Small and Sharp, 1979; Werner et al., 1979; CDC, 1984; Richwald et al., 1988) or unpasteurised cheese (Maguire et al., 1992), and not with bovine meat and meat products.

Mortality rates due to *Salmonella* infection have been reported to be around 0.5 %, but mortality associated with infection with *S.* Dublin has been reported to be around 3 % (Jones et al., 2008). Furthermore, the long-term mortality after infection with *S.* Dublin is four times higher than for other serovars (Helms et al., 2003). Based on data reported to TESSy for the period 2007 to 2011 with information on outcome of disease, no deaths have been reported linked to *S.* Dublin infection (total of 795 reported cases of *S.* Dublin, between 117 and 197 cases per year; however, data on outcome was only provided for 4.3 % of all the *S.* Dublin reported cases).

- **Evidence for meat from bovine animals as an important risk factor:** based on the evidence available and discussed below, 'Yes'

Epidemiological link. Source-attribution studies of human salmonellosis are presented in Table 6.

Contaminated bovine meat and products thereof have been implicated in a number of salmonellosis cases. Between 2007 and 2009, of the 1 404 verified outbreaks 30 were linked to the consumption of bovine meat or bovine meat products. During the years 2010 and 2011, out of the 624 strong evidence outbreaks reported, 24 were linked to the consumption of bovine meat or bovine meat products. In 2011, bovine meat and products thereof was reported as the implicated food vehicle for 6.9 % of all *S.* Typhimurium outbreaks and for 3.2 % of all *S.* Enteritidis outbreaks (EFSA and ECDC, 2013). No *S.* Dublin outbreaks were reported.

In 2010, 4.7 % of a total of 341 strong-evidence outbreaks of salmonellosis reported in the EU were associated with consumption of bovine meat and products thereof in the EU (EFSA and ECDC, 2012a). The proportion of outbreaks reported by EU MSs for the period 2007-2009 was in the range of 2 to 3 % of all verified outbreaks (EFSA and ECDC, 2010, 2011). A recent review of the EU-wide data on food-borne outbreaks during the period 2007-2009 estimated that beef and products thereof accounted as the source of approximately 0.6 % of the human salmonellosis verified outbreaks reported each year (Pires et al., 2010). This figure is

markedly lower than the proportion of reported outbreaks for the same period (i.e. 2.4 %, 30 of a total of 1 217 outbreaks) as the methodology of the Pires et al. study took into account potential biases that may be introduced by the way in which composite foodstuffs linked to an outbreak are categorised (e.g. the source of outbreaks linked to consumption of beef tartare are categorised as beef and products thereof, when the more likely source of *Salmonella* spp. is the raw eggs included in the dish). For a review on *Salmonella* source attribution methodologies including advantages and limitations see the previous EFSA Opinion on source attribution for *Salmonella* in meat (EFSA, 2008).

In 2011, there is strong evidence that 1.9 % of the reported food-borne outbreaks in the EU (13 outbreaks) were caused by bovine meat and products thereof (EFSA and ECDC, 2013). Out of these, 8 were caused by *Salmonella* spp. (6 due to *S.* Enteritidis and two due to *S.* Typhimurium). Bovine meat and products thereof was reported as the fourth most frequently reported vehicle of *S.* Typhimurium outbreaks.

Several quantitative assessments of *Salmonella* source-attribution have been recently carried out within the framework of EFSA's recent work (EFSA Panel on Biological Hazards, 2011c; Hald et al., 2012; Pires et al., 2011; Vose et al., 2011). All these have followed a common source-attribution methodology (Hald et al., 2004), but did not include bovine meat or bovine animals in the animal-food-sources because of lack of sufficiently harmonised monitoring and/or comparable prevalence data on *Salmonella* spp. in the bovine reservoir (e.g. bovine meat or bovine animals) in EU MSs.

In the EU, two MSs do carry out regular assessments of the source attribution of *Salmonella* spp. employing modelling based on microbial subtyping. In Denmark (DTU, 2012a), domestic beef accounted for 0.2 %, 0.7 % and 0.5 % of reported cases in 2009, 2010 and 2011, respectively. In the same years, imported beef accounted for 3 %, 2 % and 2.8 % of cases, respectively. As approximately 70 % of all cases were either travel-related, of unknown origin or from known outbreaks, domestic beef accounted for 0.6 %, 2.5 % and 2.0 % of cases with identified reservoirs in 2009, 2010 and 2011, respectively, and all beef for 10.1 %, 9.5 % and 13.3% of cases. In the Netherlands (Maassen et al., 2012), 16.4 % and 16.7% of reported cases were attributed to the cattle reservoir in 2009 and 2011, respectively. In these years, travel-and outbreak-related cases and unknown reservoirs accounted for 22.8 % and 16.8 %. Hence, cattle-related strains accounted for 21 %and 20 % of cases with identified reservoirs in 2009 and 2010, respectively. It must be noted that surveillance in cattle is not random in the Netherlands and the strains include those from diseased animals.

A systematic review on source attribution of human salmonellosis using a meta-analysis of case-control studies of sporadic infections has recently been published (Domingues et al., 2012b). The results of the study suggested that travel, predisposing factors, eating raw eggs and eating in restaurants were the most important risk factors for human salmonellosis. Overall, the OR of eating beef as a risk factor for sporadic salmonellosis was 0.68 (95 % C.I.=0.52-0.89), while chicken was 0.95 (95 % C.I.=0.64-1.40), pork 0.64 (95 % C.I.=0.47-0.88) and eggs 1.26 (95 % C.I.=0.90-1.80).

In expert elicitation studies (Table 6), consumption of beef was estimated to be associated with 5 to 10 % of all cases of human salmonellosis.

Carcass/animal prevalence. Cattle may carry *Salmonella* spp. in their gastro-intestinal tract and shed it in their faeces. Mean prevalence rates of 2.9 %, 60 %, 1.3 % and 3.8% have been calculated respectively for bovine faeces, hides, chilled carcasses and raw beef products (Rhoades et al., 2009). During the period 2004 to 2011, *S.* Typhimurium and *S.* Dublin were the two most frequently reported serovars in bovine animals and meat thereof (EFSA and ECDC, 2013).

In 2010 , the most recent year for which complete data were readily available (i.e. serovar distribution in cattle and beef presented separately), the distribution of *Salmonella* serovars in cattle in the EU, as reported by the MSs (EFSA and ECDC, 2011), was as follows: *S.* Typhimurium (46.1 %), monophasic *S.* Typhimurium (4.7 %), *S.* Dublin (44.3 %), *S.* Enteritidis (3.7 %), *S.* Mbandaka (2.6 %), *S.* Ohio (2.5 %), *S.* London (1.6 %), *S.* Agona (1.3 %), *S.* Montevideo (1.0 %) and *S.* Infantis (0.8 %). Seven MSs reported information on *Salmonella* serovars in bovine meat in the same year. As in previous years, *S.* Typhimurium (20.8 %) and *S.* Dublin (18.1 %) were the most common serovars, followed by monophasic *S.* Typhimurium (10 %), *S.* Enteritidis (9.2 %), *S.* Derby (7.7 %), *S.* Rissen (7.7 %), *S.* London (3.1 %), *S.* Infantis (1.9 %) and *S.* Manhattan (1.5 %). Between 2004 and 2009, up to 7.5 % of fresh meat samples taken during slaughter in Europe were *Salmonella* spp. positive (DTU, 2012b). Other recent studies have reported beef carcass contamination rates of 0.25 % and 3.5% (ProSafeBeef, 2012).

In Table 5, bovine carcass prevalence estimates in the EU show an average prevalence of 0.2% for the period 2008-2011, this ranging from 0 % to 8 % in any given MS in any given year.

Expert opinion that bovine meat consumption is a risk factor. Based on the information and data presented above, including considerations on beef frequently being consumed raw or undercooked, expert opinion concludes that consumption of bovine meat is an important risk factor.

Overall, owing to data gaps there is uncertainty in the extent to which bovine meat contributes to human salmonellosis, and unequivocal priority ranking is difficult. Based on the data available and on the considerations presented above, including the consideration to be given to bovine animals as an important reservoir of *S.* Dublin and the severity of infection with this serovar in humans, the priority ranking for *Salmonella* spp. is currently assessed to be **'High'**.

Collecting more EU-wide data (e.g. prevalence of *Salmonella* spp. in bovine animals or bovine meat) should allow the inclusion of bovine meat in source attribution studies at EU level. An EU-wide baseline survey of *Salmonella* spp. in bovine animals or bovine meat could be considered in order to investigate the role of the bovine reservoir as a source of human infections via bovine meat, dairy products or environmental contamination by cattle.

With regards to antimicrobial resistance, data on the occurrence of ESBL/AmpC gene-carrying *Salmonella* spp. in cattle and/or beef as in the case of data on ESBL/AmpC gene-carrying *E. coli*, are limited. In addition, EU-wide TESSy data are not available. Nevertheless, although MSs are not required to screen food or veterinary *Salmonella* spp. isolates for cefotaxime resistance, some data are available and would suggest that a low percentage of bovine *Salmonella* spp. isolates display ESBL/AmpC mediated resistance. Between 2007 and 2009 (inclusive) the percentage of *Salmonella* bovine animal isolates displaying resistance to cefotaxime, ceftazidime and/or ceftiofur ranged from 0 to 0.4 % (EFSA Panel on Biological Hazards, 2011a). Bearing in mind that the outcome of the priority ranking for all *Salmonella* spp. was high, ESBL/AmpC-producing strains of this pathogen are encompassed within this category.

The same limitations as for ESBL/AmpC gene- carrying *E. coli* exist when interpreting the relevance of the food-borne and meat-borne transmission of this biological hazard (EFSA Panel on Biological Hazards, 2011a). Thus, in cases where a similar gene pattern in humans and animals may be found, there is always the possibility of food-borne or contact or environmental transmission.

Sarcocystis hominis

Sarcocystis is a genus of cyst-forming coccidia belonging to the phylum Apicomplexa. These parasites have an obligatory two-host life cycle. Infection of the intermediate host by ingesting oocysts/sporocysts results in muscle cyst formation, whereas eating meat of infected animals by the final host will result in the production of oocysts, which are excreted with the faeces. Cattle are intermediate hosts of three *Sarcocystis* spp. of which *S. hominis* is the only zoonotic species (Tenter, 1995): man is an obligatory host for *S. hominis,* while bovine animals are intermediate hosts. The prevalence of *Sarcocystis* spp in adult bovine muscle is close to 100 % in most regions of the world where it has been studied and *S. hominis* appears to account for a large proportion of these infections: based on molecular methods, *S. hominis* was identified in 60/67 (89.5 %) of Belgian raw minced beef samples (Vangeel et al., 2007). In cattle, sarcocystosis is occasionally associated with clinical syndromes and pathologies: acute sarcocystosis (Dalmeny diseases) is a rare disease; eosinophilic myositis, is a rare, specific, subclinical myopathy resulting in carcass and meat condemnation (Vangeel et al., 2012). Bovine meat is the unique source of *S. hominis,* but its relevance for overall human zoonotic sarcocystosis is unknown.

- **Human incidence:** no EU-wide data available, but considered to be 'Low'

  No information is available at EU level on human sarcocystosis, as this is not a notifiable disease in Europe. Furthermore, no recent data on human intestinal sarcocystosis in Europe are available, where studies date back about 15 years (FERA et al., 2010b) when the prevalence of human intestinal sarcocystosis (based on microscopic examination of faecal samples, which does not allow distinguishing between *S. suihominis* and *S. bovihominis*), was reported to be between 1.6 % and 10.4 %. On the other hand, world wide incidence in humans is estimated to be between 6 % and 10 % (CFSPH, 2005).

- **Severity of disease:** no EU-wide data available, but considered to be 'Low'

  The clinical course of *S. hominis* infection in humans is usually mild and in many cases asymptomatic, although the severity is correlated with the number of ingested sarcocysts. Infection may be associated with transient non-specific gastrointestinal symptoms (Fayer, 2004).

- **Evidence for meat from bovine animals as an important risk factor:** As both incidence and severity are considered low, this section is not addressed. Nevertheless, bovine meat is the only source of this zoonoses.

  It can be assumed that *Sarcocystis* spp., including the zoonotic species, are circulating in most European food animal populations, though seemingly without major impact on public health as this has not been reported. Current detection methods and reporting of *Sarcocystis* spp. are variable within the EU, and it is mostly those species causing economic impact leading to carcass condemnation in meat inspection that are detected. The sensitivity of current detection methods is limited and they cannot differentiate the zoonotic species (in cattle *S. hominis*) from the non-zoonotic ones (in cattle *S. cruzi*, *S. hirsuta*). A unified scheme for monitoring sarcocystis cannot be justified at this stage based on public health needs without further evidence of clinically significant human cases being directly linked to this parasite.

Therefore, based on the considerations presented above the priority ranking for *Sarcocystis* spp. is assessed to be '**Low**'. This result is not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures). Therefore *Sarcocystis* spp. is not considered further in this Opinion.

Taenia saginata

T. saginata or the beef tapeworm is transmitted between humans (definite host) and cattle (taurine, zebu and buffalo) (intermediate host). It has a worldwide distribution.

Humans acquire infection by eating raw or undercooked bovine meat containing viable cysticerci, the metacestode larval stage of the parasite. The tapeworm develops in the small intestine and becomes sexually mature in about three months, producing gravid proglottids, which are mobile and either migrate from the host's anus spontaneously or are shed in the faeces. The adult tapeworm can survive in the definitive host for several years. Cattle become infected by ingesting eggs while grazing or via contaminated feeds. Eggs may remain infected in the environment for up to eight months. Following ingestion, eggs hatch and oncospheres are released, penetrate the intestinal mucosa and migrate via the general circulation to skeletal and cardiac muscles where they develop into cysticerci. These become infective in about 10 weeks. They begin to degenerate within a few months after infection, and by 9 months a substantial proportion of them are dead and calcified (WHO et al., 2005). No clinical signs accompany this infection in cattle.

Consumption of bovine meat containing viable cysticerci is the only possible exposure pathway. Cysticerci in the meat are destroyed by heating (>60 °C throughout) or freezing (at least 10 days at temperature of less than -10 °C) but remain infective at 4 °C for several weeks.

According to the EU Directive No 854/2004, all bovine animals over six weeks of age have to be individually inspected for cysticercosis by visual observation and by cuts in mastication muscles (i.e. the masseter and pterygoid muscles) and the heart. The tongue and the diaphragm may be further incised if cysticerci are found in order to assess the intensity of the invasion. If an animal has a generalised infection, the carcass and offal are declared unfit for human consumption. If the infection is localised, any cysticerci found must be removed and the carcass has to be stored at a temperature not exceeding -10°C for ≥ 14 days before release for human consumption. However, current meat inspection procedures have been shown to be insufficient to eliminate the parasite in the EU.

The sensitivity of routine meat inspection for detection of bovine cysticercosis is generally considered low. Published studies report sensitivities ranging from 17 to 71 %. This variability found may be attributable to differences in inspection practices and to differences in the parasite load. Most animals are lightly infected and only a proportion of the cysts (25 %) are located in the so-called predilection sites that are inspected. In addition, the success of the method is highly dependent on the skills and the motivation of the meat inspector and on the stage of degeneration of the cysticerci. In European countries, the prevalence of bovine cysticercosis, mostly estimated from meat inspection results, varies between 0.01 and 6.8 % (SCVMPH, 2000b; Dorny and Praet, 2007). Published reviews show that between 0 and 0.45 % of cattle were found to be infected with *T. saginata* cysticerci in the period 2004-2011 when assessed during routine *post-mortem* inspection in 14 EU MSs[11] for which data were available (Allepuz et al. 2011; FERA et al., 2010a). Many MSs do not report cysticercosis status, and the large differences in prevalence that exist between countries cannot be explained by differences in farm management systems.

Heavy infections in cattle are rather uncommon and are mostly associated with the presence of a human tapeworm carrier on the farm, illegal application of sludge from septic tanks on pasture or crops, by indiscriminate defecation associated with camping and tourism, or by grazing on pastures in close proximity to sewage treatment plants. Light infections are much more common. They are the result of accidental ingestion of eggs that are disseminated in the environment. How these eggs are

11 Austria, Belgium, Czech Republic, Denmark, France, Germany, Italy, Lithuania, Luxemburg, Netherlands, Poland, Portugal, Spain and United Kingdom. Data from Belgium made available by the Belgian Federal Agency for Security of the Food Chain.

spread from tapeworm carriers, who often live in urban areas, to rural areas is not well known, but it is clear that sewage treatment plants and water streams are pivotal in this dissemination. The processing of sewage sludge and the delay before its application to a pasture will affect the possibility of transmission. The standard application of sludge on pastures does not seem to be an important risk factor (Cabaret et al., 2002). In contrast, infection of cattle appears to be more often associated with flooding of pastures, free access of cattle to surface water, and proximity of wastewater effluent. Demographic pressure has also been suggested to be a risk factor, as higher population densities can increase the risk of bovine cysticercosis (Boone et al., 2007).

Persistence of the parasite in the EU is believed to be due to: (1) the low sensitivity of meat inspection; (2) grazing of cattle resulting in exposure to infection from the environment; (3) dissemination of eggs through water treatment plants and effluents; (4) open air defecation related to tourism and sport activities; and (5) eating of raw and undercooked beef (Dorny and Praet, 2007).

- **Human incidence:** no EU data available, but considered to be 'Low'

  No information is available on the incidence of *T. Saginata infection* in humans in the EU, where this is not a notifiable disease.

  Based on data from sales of cestodicidal drugs (FERA et al., 2010a) the incidence could be estimated to be between 0.5 and 1 per 100 000 population. Differences between MSs cannot be explained by differences in culinary habits only.

- **Severity of disease:** no EU-wide data available, but considered to be 'Low'

  In humans, infection is characterised by mild intestinal disorders and weight loss, both of which can be absent, and by anal pruritus. Occasionally, taeniosis may be accompanied by more severe symptoms, such as diarrhoea, nausea, and very rarely intestinal perforation and peritonitis (FERA et al., 2010a)

- **Evidence for meat from bovine animals as an important risk factor:** As both incidence and severity are considered low, this section is not addressed. Nevertheless, bovine meat is the only source of this zoonosis.

Therefore, based on the considerations presented above the priority ranking for *Taenia saginata* is assessed to be '**Low**'. This result is not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures). Therefore *Taenia saginata* is not considered further in this Opinion. Nevertheless, a final consideration is made in Section 5.4 on the effect on this hazard of the proposed generic bovine meat (carcass) safety assurance framework.

Toxoplasma gondii

Toxoplasma gondii is an apicomplexan parasite. It belongs to the family *Sarcocystidae* and is the only species in the *Toxoplasma* genus. It is an obligate, intracellular and cyst-forming parasite. *T. gondii* is one of the most successful and widespread parasites.

The life cycle of *T. gondii* is complex and has three distinct infectious stages: the tachyzoites, the bradyzoites and the sporozoites. *T. gondii* has a wide variety of hosts, as almost all warm blooded animals can be infected. Sexual replication of the parasite occurs only in domestic cats and wild felidae (definite hosts), while asexual replication occurs in both intermediate and final hosts. Intermediate hosts comprise humans and most warm-blooded animals (Frenkel, 1970; Tenter et al., 2000). In humans, it can cause congenital infection resulting in mild to severe infection of the foetus; it is also an opportunistic parasite in immunosuppressed individuals and an occasional cause of disease

in immunocompetent persons. It is one of the most important causes of infectious abortion in small ruminants (Tenter et al., 2000).

- **Human incidence:** based on EU data on congenital toxoplasmosis, 'Low'

  The incidence of congenital toxoplasmosis in the EU in 2011 was reported to be 0.01 cases per 100 000 population. However, the incidence of acquired toxoplasmosis is difficult to establish as the infection is usually asymptomatic (80-90 %) or causes only mild symptoms, and also as part of the symptomatic cases (between 15-20 %) are not diagnosed as toxoplasmosis (EFSA, 2007b). Together these factors contribute to toxoplasmosis being considered as an under-detected and under-reported disease.

  According to data from the early 1990s, the seroprevalence reported in the EU ranged from 8.1 % in the United Kingdom (UK) to 77.4 % in the former Yugoslavia (ACMSF, 2012). Recent EU-wide data on human seroprevalence of toxoplasmosis are not readily available, although some national estimates are available, for example 25 % in the Netherlands (Hofhuis et al., 2011) and 20 -40 % in the UK (ACMSF, 2012).

- **Severity of disease:** based on EU data for congenital toxoplasmosis, 'High'

  In 2010, the latest year for which congenital toxoplasmosis severity data are available, 5.15 % of reported confirmed cases of congenital toxoplasmosis in the EU resulted in death. In 2009 this value was 9.62 %.

  In most people acquired toxoplasmosis infection is asymptomatic (80-90 %) or resulting in a mild and self-limiting influenza-like disease. However, the outcome of the disease can also include chorioretinitis. More recent literature points to the potential link between *T. gondii* infection and disorders such as schizophrenia or behavioural changes (Flegr, 2007; Anon, 2012; Yolken et al., 2009).The value of the DALY estimates from the Netherlands in 2009 for acquired toxoplasmosis is 3 170, the highest of all the hazards considered in this assessment.

- **Evidence for meat from bovine animals as an important risk factor:** based on the evidence available and discussed below, 'Undetermined'

  Epidemiological link. There are no EU-wide data on source attribution of toxoplasmosis and, overall, toxoplasmosis source attribution is a matter of debate. In particular, the importance of beef as a source of human infection is uncertain. The BIOHAZ Panel considered the following:

  - Dubey and Jones (2008) state that "*The ingestion of beef or dairy products is not considered important in the epidemiology of T. gondii because cattle are not a good host for this parasite. However, we cannot be sure that beef does not play a role in T. gondii transmission as only relatively small amounts of beef have been tested for viable T. gondii parasites*." These authors also describe two outbreaks that have been attributed to consumption of beef (Dubey and Jones, 2008).

  - Results of available source attribution estimates of human cases of those hazards related to consumption of bovine meat are presented in Table 5. Note that no source-attribution estimates are available at EU-wide level. Instead, the results of country-specific estimates based on published literature are presented.

  - The fraction of cases attributable to food-borne exposure was estimated to be 50 % in the USA (Mead et al., 1999) and 56% in the Netherlands (Havelaar et al., 2008).

- Using a newly developed serological assay, Boyer et al. (2011) found that 59 of 76 (78 %) mothers of congenitally infected infants in the USA had primary oocysts infection. Oocyst exposure can occur through environmental sources (e.g. gardening or contact with cat faeces), but also through food (e.g. fruits and vegetables).

- The marked decrease in *T. gondii* infection in pigs in the last decades, which is the result of controlled housing conditions, has made the relative contribution of meat from other species, including bovine meat, more important. Based on expert elicitation studies in the USA (Hoffmann et al., 2007) and the Netherlands (Havelaar et al., 2008), it is estimated that 23% of all food-borne exposures are associated with beef. Hence, the fraction of all cases of human toxoplasmosis associated with consumption of beef is estimated at 12-13%.

- The presence of tissue cysts has been demonstrated in beef (Dubey and Thulliez, 1993) and congenital transmission is possible although very rare, and most cases could not be confirmed (Canada et al., 2002; Dubey, 1983; Dubey, 1986). There are some indications that cattle are capable of clearing tissue cysts with time, and this is followed by a drop in their antibody titres (Dubey, 1983). Generally, bovine meat has been less frequently associated with human infection. In a large study using a cat bioassay to detect *T. gondii* in pork, bovine and chicken meat samples purchased in retail stores in the USA no evidence of infection was found in the 2 094 beef samples (Dubey et al., 2005). Recently, a correlation between the presence of tissue cysts and seropositivity in cattle has been questioned and *T. gondii* DNA has been isolated from seronegative animals (Opsteegh et al., 2011). Using a newly developed PCR assay, these authors detected *T. gondii* DNA in 2 % of beef samples in the Netherlands. However, the finding of DNA in meat samples does not necessarily mean that viable parasites are present.

- A European multicentre study carried out in centres in Naples, Milan, Copenhagen, Oslo, Brussels, and Lausanne is a key reference (Cook et al., 2000). In this study it was estimated that 30 to 60 % of the infections were acquired through consumption of meat and 6 to 17 % were soil-borne. The statistically significant risk factors identified were: consumption of meat other than beef, lamb or pork (OR=4.12); consumption of raw/undercooked lamb (OR=3.13); travel outside Europe, the USA or Canada (OR=2.33); contact with soil (OR=1.81); consumption of raw/undercooked beef (1.73); and tasting of meat during cooking (OR=1.52). Consumption of raw/undercooked pork was not significantly associated with *T. gondii* infection (OR=1.4 (95% C.I.: 0.7-2.8)). This study also found that the most important meat source varied by country (which is probably due to differences in consumption habits) and that a large proportion of the infections remained unexplained (14-49 %).

– A prospective case-control study designed to identify preventable risk factors for *T. gondii* infection in pregnancy was conducted in Norway (Kapperud et al., 1996). Case-patients were identified through a serologic screening program encompassing 37 000 pregnant women and through sporadic antenatal testing for *Toxoplasma* infection. A total of 63 pregnant women with serologic evidence of recent primary *T. gondii* infection and 128 seronegative control women matched by age, stage of pregnancy, expected date of delivery, and geographic area were enrolled. The following factors were found in conditional logistic regression analysis to be independently associated with an increased risk of maternal infection (in order of decreasing attributable fractions): 1) eating raw or undercooked minced meat products (OR=4.1, p=0.007); 2) eating unwashed raw vegetables or fruits (OR=2.4, p=0.03); 3) eating raw or undercooked mutton (OR=11.4, p=0.005); 4) eating raw or undercooked pork (OR=3.4, p=0.03); 5) cleaning the cat litter box (OR=5.5, p=0.02); and 6) washing the kitchen knives infrequently after preparation of raw meat, prior to handling another food item (OR=7.3, p=0.04). The only data that might

discredit beef and beef products are connected to the item "eating raw or undercooked minced meat products (OR=4.1, p=0.007)". Nearly at the same time an investigation of antibodies to *T. gondii* in Norwegian livestock including cattle was performed (Skjerve et al., 1996). Of the 1 053 slaughtered cattle representing nine different slaughterhouses and regions in Norway 54 (5.1 %) were positive. The grazing areas and strategies of cattle are different from those in sheep, and this might explain the lower prevalence in cattle. However these results are not easy to interpret: the lack of specificity of the ELISA may overestimate the incidence. Based on Dubey et al. (1988) the authors concluded that the results "*do not indicate that there is any health hazard for consumers eating raw or undercooked beef, although some cattle may have been exposed to cysts of T. gondii"*.

Carcass/Animal prevalence. Bovine animals can be infected by *T. gondii* and the seroprevalence can be high. Available data from 2008 to 2010 in the EU (EFSA and ECDC, 2012a) indicate seroprevalence in bovine animals in individual MSs ranged from 0 % to 95.5% (when more than 10 bovine animals have been sampled in a given year). Sampling context included clinical investigation, surveyance and monitoring. Serological studies in cattle are not easy to complete because the sensitivity and specificity of several tests for human diagnosis are too low for test on cattle sera, resulting in a poor discriminative power (Dubey, 1986; Dubey and Thulliez, 1993; Lopes et al., 2012; Opsteegh et al., 2011).

Recent studies by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)[12] have evaluated the presence of viable parasites in muscle samples (i.e. cardiac tissue) from cattle (Halos et al., 2011).The researchers have analysed meat samples, of which more than 2 300 hearts from French cattle and almost 600 diaphragm samples from imported cattle. All samples were tested by serology using the mean antibody titre (MAT) technique. Seroprevalence in veal calves was 3 % and 18 % in beef. Every week, the five samples with highest titres in MAT were selected for testing of viable organisms by mouse bioassay. In total, 207 samples were tested in the bioassay. Titres in these samples varied between 0 (no antibodies detected) to 1:400. Two samples allowed an isolation of viable *T. gondii* parasites, presenting MAT titres of 1:25 and 1:50, respectively. This is the first time that viable, infectious *T. gondii* has been detected in muscle samples (i.e. cardiac tissue) from cattle. The results also confirm that serology is of limited significance in the diagnosis of the infection status of cattle. It is currently not known how these results can be translated into risk for human exposure to *T. gondii* through consumption of carcass muscle.

***Expert Opinion that bovine meat consumption is a risk factor*.** In conclusion, there is some evidence that infectious organisms can be present in beef, but their prevalence appears to be low. Considering that beef is frequently consumed raw or undercooked, even low prevalence may be associated with higher risks than consumption of other species such as pork and poultry.

Based on the data available and on the considerations presented above, the priority ranking for *Toxoplasma gondii* cannot be assessed at this time and thus it is carachterised as '**Undetermined**'. It is advisable to collect more data on the potential for infectious transmission to humans of *Toxoplasma gondii* via consumption of bovine meat from infected animals and on the overall significance of the different human exposure pathways.

[12] Results of this ANSES funded study were kindly presented by Dr. Radu Blaga on the 4th of December 2012 during the meeting of the working group drafting this Appendix of the scientific opinion.

2.2.3.3. Summary results of the priority ranking of identified hazards

Table 7 provides a summary of the priority ranking outcome for the identified bovine meat-borne hazards.

Table 7: Final priority ranking of the identified bovine meat-borne biological hazards according to the decision tree in Figure 1. None of the low-priority results are due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures).

Hazard	High notification rate in humans? (high: ≥ 10/100 000)	High severity (% deaths over confirmed cases? high: ≥ 0.1 % in more than one year)	Evidence for meat from bovine animals as an important risk factor (see Section 2.2.3.2)	Priority category
Bacillus anthracis	No	Yes	No	Low
Campylobacter spp. (thermophilic)	Yes	–[1]	No	Low
Pathogenic VTEC	No	Yes	Yes	**High**
ESBL/AmpC gene-carrying *E. coli*	NA[2]	Unclear[3]	Unclear	**Undetermined**
Salmonella spp.	Yes	–	Yes	**High**
Sarcocystis hominis	No	No	–	Low
Taenia saginata	No	No	–	Low
Toxoplasma gondii	No[4]	Yes[4]	Unclear	**Undetermined**

[1]No need for evaluation according to the decision tree.
[2]No data available.
[3]Based on published evidence.
[4]Based on congenital toxoplasmosis and DALYs.

Because the hazard identification and ranking relate to the EU as a whole at the time of preparation of this document, refinements reflecting differences between regions or production systems are recommended if/where/when hazard monitoring data indicate.

Furthermore, as new hazard(s) might emerge and/or hazards that are not currently a priority might become more relevant over time or in some regions, the risk ranking should be revisited regularly.

To provide a better evidence base for future rankings, studies should be undertaken to:

- systematically collect data for source attribution for the identified bovine meat-borne hazards; and
- collect data to identify and rank emerging bovine meat-borne hazards.

2.3. Conclusions and recommendations for hazard identification and priority ranking

All biological hazards reported in reviewed published literature as potentially associated with bovine animals and/or their meat were identified and listed. Those for which there was no evidence of transmission via handling during preparation for consumption and consumption of bovine meat (including *Mycobacterium bovis*) or were identified as of no relevance to the EU were excluded from consideration.

Biological hazards identified as potentially transmissible through bovine meat and currently present in the EU bovine animal population included: *Bacillus anthracis*, *Bacillus cereus*, *Campylobacter* spp. (thermophilic), *Clostridium botulinum*, *Clostridium perfringens*, *Listeria monocytogenes*, pathogenic

verotoxygenic *Escherichia coli* (pathogenic VTEC), extended spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene-carrying bacteria, *Salmonella* spp., *Staphylococcus aureus, Sarcocystis hominis, Toxoplasma gondii,* and *Taenia saginata*.

A decision tree was developed and used for priority ranking bovine animal meat-borne biological hazards. The term 'priority' substituted here the term 'risk' employed in previous related EFSA Scientific Opinions on public health hazards to be covered by meat inspection of swine and poultry. This is because it was determined that, in the absence of sufficient EU-wide data for bovine meat, the term 'priority' would be more appropriate than the term 'risk' when categorising the relevance of a hazard to meat inspection.

The first step of the decision tree excluded hazards that are introduced and/or for which the risk to public health is associated with growth after carcass chilling (i.e. *L. monocytogenes,* and toxins of *B. cereus, C. botulinum, C. perfringens* and *S. aureus*). Bovine meat-borne biological hazards subjected to complete evaluation through the decision tree were those identified as potentially present on chilled bovine carcasses and that are controlled primarily by measures during the farm-to-chilled carcass phase. They included *B. anthracis, Campylobacter* spp. (thermophilic), *Salmonella* spp., pathogenic VTEC, ESBL/AmpC gene-carrying *E. coli, S. hominis, T. gondii,* and *T. saginata.*

Further priority ranking (as high or low) of the identified hazards was based on the assessment of the following: (i) the magnitude of human health impact based on incidence of confirmed human cases reported to ECDC, (ii) the severity of the disease in humans based on fatalities, and (iii) the strength of evidence that meat from bovine animals is an important risk factor for the disease in humans. Further, the priority was characterised as 'undetermined' if the data available for the assessment of a given biological hazard were insufficient to conclude on the ranking. For hazards assessed as low-priority, it was further assessed whether falling into this category was due to currently applied controls (i.e. any hazard-specific control measure implemented at farm and/or slaughter level before chilling of the carcass, including current meat inspection procedures).

Based on the limited data available and expert opinion, biological hazards categorised as low-priority for bovine meat inspection were *Bacillus anthracis*, *Campylobacter* spp. (thermophilic), *Sarcocystis hominis* and *Taenia saginata*. These hazards were not considered further because it was determined that their low-priority ranking was not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures). However, the effect of carcass chilling on reduced survival of *Campylobacter* spp. (thermophilic) on carcasses of bovine animals as a non-hazard-specific control measure has to be taken into account.

The bovine meat-bone biological hazards categorised as of high-priority for meat inspection were *Salmonella* spp. and pathogenic verotoxigenic *Escherichia coli* (pathogenic VTEC).

Toxoplasma gondii and ESBL/AmpC gene carrying *E. coli* were carachterised as of 'undetermined' priority for bovine meat inspection because available data were insufficient for conclusive ranking.

Hazard identification and associated priority or risk ranking should be revisited regularly as new hazards might emerge and/or hazards that presently are of undetermined or low-priority might become more relevant in the future, in some regions, or as more data become available.

To provide a better evidence base for future rankings the following should be undertaken: (i) systematic collection of data for source attribution of the identified bovine meat-borne hazards, and (ii) collection of data to identify and rank emerging bovine meat-borne hazards.

Collection of more EU-wide data on prevalence of *Salmonella* spp. in bovine animals or bovine meat should allow the inclusion of bovine meat in source attribution studies. An EU-wide baseline survey of

Salmonella spp. in bovine animals or bovine meat could be considered in order to investigate the role of the bovine reservoir as a source of human infections via bovine meat, dairy products or environmental contamination by cattle.

Collection of more data on the potential for infectious transmission to humans of *T. gondii* via consumption of bovine meat from infected animals and on the overall significance of the different human exposure pathways should be undertaken.

Since *Campylobacter* spp. (thermophilic) is an important cause of human infection and because currently there is uncertainty in the extent to which bovine meat contributes to human campylobacteriosis, new information should be carefully monitored as and when it becomes available.

Since there is uncertainty as to the role of and the extent to which bovine meat contributes to ESBL/AmpC resistance in humans, new information should be carefully monitored as it becomes available.

3. Assessment of strengths and weaknesses of current meat inspection of bovine animals from a meat safety perspective

Before or, at the latest, on their arrival at the slaughterhouse, available FCI on the bovine animals is considered, as indicated below. At the slaughterhouse, animals are also subjected to *ante-mortem* examination conducted at the time of arrival (i.e. unloading), during resting (i.e. in the lairage pen), and—in the case of prolonged resting time— again shortly before slaughter. Additionally, in the case of animals suspected of carrying disease, more detailed *ante-mortem* examination is conducted in a detention pen. After slaughter, *post-mortem* examination of organs and carcasses is conducted macroscopically, followed by sampling for laboratory testing as required.

The differences in meat inspection procedures between bovine animals younger and older of six weeks of age reflect inherent differences in the conditions or pathologies that can occur in animals in these age categories. Thus, for example, the udder is included in the inspection procedure of older bovine animals as these could show abnormalities such as mastitis. On the other hand, in younger bovine animals the umbilical region and the joints are inspected in detail as these could show signs of generalised septicaemia. The occurrence of bovine cysticercosis is not inspected via incision of the masseter muscles in cattle younger than 6 weeks old, as the cyst become visible by six weeks after infection (OIE, 2012). Details of meat inspection procedures used in bovine animals can be found in Regulation (EC) No 854/2004.

3.1. Food chain information (FCI)

Ideally, the FCI on bovine animals should include data on individual animal identification and movement, epidemiological intelligence (data from herd health plans, monitoring and surveillance, medicines and veterinary treatments), farm management, and quality assurance (QA), i.e. welfare, housing and handling facilities, feed composition, storage and use, and biosecurity, and environmental management (SCVMPH, 2000a, 2001).

3.1.1. Strengths of the current FCI

FCI related to identification of individual animals is a pre-requisite for implementation of traceability systems further along the food chain. In addition, consideration of FCI is useful for differentiation between bovine animals coming from integrated and non-integrated production systems; normally, FCI for bovine animals coming from integrated systems is more comprehensive and reliable. FCI on farm management and production data can be useful when considering the general status of incoming animal batches; usually, better farm management and production parameters are associated with better general condition of animals. Furthermore, FCI data on herd health, veterinary treatments/medicines, and on-farm monitoring/surveillance of hazards and diseases is useful when assessing the likelihood of the presence of certain diseases, abnormalities, residues or hazard carriage in incoming batches.

In the current meat inspection system for bovine animals, FCI is of particular importance relative to bovine tuberculosis (bTB), bovine spongiform encephalopathy (BSE), and brucellosis. Although bTB is not included in the list of meat-borne pathogens identified in this Opinion, because of its prominence in the current meat inspection system and for historical reasons, the following is presented for clarification as to how it is addressed. EU MSs/regions are designated either as Officially Tuberculosis Free (OTF) or non-OTF. In non-OTF regions, animals suspected of having tuberculosis, based on FCI (i.e. clinical evidence or results of diagnostic tests on-farm), are required to be segregated in the lairage and undergo separate slaughter and dressing under hygienic operational conditions in order to minimize the likelihood of cross-contamination of other animals or carcasses. Also, those animals undergo more detailed ante and *post-mortem* examinations in order to detect any tuberculous lesions and assess whether they are localised or generalised. In the case of BSE, FCI enables verification that the bovine animals are eligible to be slaughtered for human consumption and directs BSE-related *post-mortem* testing and handling of the specified risk materials (SRM).

FCI sometimes includes data on the use (or otherwise) of effective environmental and sanitary measures and/or serological testing for *T. saginata* cysticercus on-farm, which can indicate the farms that are heavily contaminated with the parasite and can help to decide how detailed the related *post-mortem* examination needs to be.

Overall, where available, complete and reliable FCI enables differentiation of batches of bovine animals posing higher or lower overall meat safety risk. Such differentiation helps to identify higher-risk batches that may require particular attention during ante- and *post-mortem* examinations and, if needed, the application of specific measures to ensure meat safety. Furthermore, FCI also enables flow of information from slaughterhouses back to farms. This information may be used for optimisation of on-farm controls (e.g. data on diseases/abnormalities detected at meat inspection and results from additional testing for hazards in slaughtered animals). Currently, it seems that such feedback is used primarily in relation to diseases notifiable in the EU and/or MSs (e.g. bTB, BSE and brucellosis), although evidence suggests that it is largely underutilised or not used in the case of other hazards/conditions (DAFC, 2011; EFSA, 2012).

3.1.2. Weaknesses of the current FCI

Findings from a recent questionnaire survey of the current practices in the EU indicated that FCI relating to the high-priority meat-borne hazards identified in this Opinion is used only to a limited extent and in a non-harmonised way within the current system of meat inspection of bovine animals (DAFC, 2011). For example, the *Salmonella* status of animals was part of the FCI only in 36% of the responses. Therefore, the use of FCI is currently mainly limited to batches of bovine animals coming from herds under restriction due to brucellosis, tuberculosis, or other controlled diseases including BSE, and it is underutilised or not used for high-priority biological hazards (i.e. *Salmonella* spp. and pathogenic VTEC).

3.2. *Ante-mortem* inspection

All bovine animals presented for slaughter must be examined *ante-mortem*, which is usually conducted by visual observation of animals in motion: on arrival, i.e. during unloading, and, in the case of extended lairaging, again just before sending them from lairage to slaughter.

3.2.1. Strengths of *ante-mortem* inspection

The strengths of *ante-mortem* examination are particularly related to animal welfare and animal health aspects, which are not dealt with in this Appendix of the Opinion. The main strength of *ante-mortem* examination from a public health perspective is that its findings (particularly in combination with FCI) can be the basis for key decisions relative to: a) whether animals can progress to slaughter normally or should be separated from the normal slaughter; b) which animals must be removed from the food chain; and which animals need more detailed *post-mortem* examination.

A further strength of *ante-mortem* examination is that of visual cleanliness of bovine animals presented for slaughter can also be assessed. It is considered that the key source of microbiological contamination of bovine carcasses while in the slaughterline is the hide of slaughtered cattle, as hide-to-carcass cross-contamination cannot be entirely prevented under commercial conditions (Bell, 1997; Blagojevic et al., 2012b; Elder et al., 2000; Vivas-Alegre and Buncic, 2004; Antic et al., 2010). Cattle hides carry up to 11 log units CFU/cm^2 of aerobic bacteria (Antic et al., 2010), which may include important meat-borne pathogens, such as pathogenic VTEC (including VTEC O157), *Salmonella* spp. and *Campylobacter* spp. (thermophilic), and consequently can cross-contaminate carcass meat (Arthur et al., 2002; Avery et al., 2002; Bell, 1997; Buncic and Sofos, 2012; Collis et al., 2004; Elder et al., 2000; Reid et al., 2002; Sofos et al., 1999).

Regulation (EC) No 853/2004 specifies that 'animals must be clean' when processed in slaughterhouses. Visual scoring of hide cleanliness before slaughter of bovine animals in practice varies in different countries such as the UK, Ireland, Finland and Australia (Davies et al., 2000; EFSA, 2012; McEvoy et al., 2000; Ridell and Korkeala, 1993). The aim of scoring is to ensure that excessively dirty animals are not sent from the farm to slaughter or that slaughtering is performed logistically (dirty animals slaughtered after clean animals), at slower line speed, with increased process hygiene controls applied more carefully (Ridell and Korkeala, 1993; Longstreeth and Udall, 1997). An alternative approach is the pre-slaughter washing of live bovine animals, which, although practised to some extent in non-EU countries, has been reported as impractical and microbiologically variable or ineffective (Bell, 1997; Mies et al., 2004).

3.2.2. Weaknesses of *ante-mortem* inspection

The arrival for slaughter of large numbers of animals at or about the same time, all or the majority of which appear healthy on initial observation, reduces the opportunity and feasibility to perform a comprehensive clinical examination on every individual animal. Usually, live bovine animals are visually examined in groups and only those showing obvious abnormalities and/or behaviour are subjected to more detailed examination.

Healthy bovine animals may asymptomatically carry or shed the currently identified high-priority meat-borne hazards (e.g. *Salmonella* spp. and pathogenic VTEC), which cannot be detected by *ante-mortem* examination. Bovine animals not showing any abnormalities at *ante-mortem* group examination may suffer from subclinical diseases or infections of public health relevance (e.g. *T. saginata* cysticercus).

3.3. *Post-mortem* inspection

Post-mortem examination of slaughtered bovine animals is conducted macroscopically (i.e. visual, palpation, incision) at multiple inspection point(s) in the slaughterline and involves examination of: the head and pluck (i.e. organs of thoracic cavity); abdominal organs; the carcass as it undergoes dressing; and a final carcass inspection prior to application of health inspection marking. The description of *post-mortem* procedures in the EU can be found in Regulation (EC) No 854/2004, and also in Appendix C of this Opinion.

3.3.1. Strengths of *post-mortem* inspection

As in the case of *ante-mortem* inspection, the strengths of *post-mortem* examination of bovine animals are particularly related to animal health and welfare aspects, which are not dealt with in this Appendix of the Opinion. These include detection of specific animal (i.e. non-zoonotic and/or non-food-borne) and identification of meat quality-related abnormalities such as dark, firm and dry (DFD) meat, or bruising, which are primarily indicators of welfare problems.

Some classical zoonotic diseases (e.g. tuberculosis, brucellosis) can be detected by *post-mortem* examination. However, they have become well controlled in many areas where modern systems of animal husbandry, disease control and animal health care have been introduced. Hence, the ability of

current *post-mortem* examination to macroscopically detect lesions potentially caused, not only by mycobacteria or brucellosis, but also by *T. saginata* cysticercosis, is relevant only in regions where they are present. In addition, the first two diseases - although zoonotic - are not meat-borne, as assessed previously.

Septicaemia (i.e. the presence of various pathogenic microorganisms in the blood, e.g. *Streptococcus* spp., *Salmonella* spp.), which is an acute, systemic and always serious condition, is expected to be detected sometimes before slaughter (on-farm or at *ante-mortem* inspection). However, septicaemia associated with some foci of infection in tissue like abscesses may be less acute and is detectable only at *post-mortem* examination. It should be noted that septicaemia-causing organisms – even those that are zoonotic - are not always meat-borne (e.g. *Streptococcus* spp.). Routine inspection procedures under slaughterhouse conditions do not differentiate organisms causing septicaemia, i.e. if they are zoonotic and whether they are meat-borne; hence any carcass with suspected lesions indicating septicaemia is condemned.

Bovine carcasses are also inspected for the presence of faecal contamination/stains during *post-mortem* examination. Any faecal stains are then removed by the Food Business Operator (FBO) through trimming of the contaminated part of the carcass. Significant reductions in carcass contamination due to trimming have been shown in studies in which the operatives were instructed to immerse their knives and hooks in water at 82°C or higher prior to touching the carcass (Kochevar et al., 1997; Prasai et al., 1995; Reagan et al., 1996). In contrast, other studies reported no effect on carcass decontamination (Gill et al., 1996; Miller et al., 1995). However, in the latter studies the operatives were not instructed to immerse their knives and hooks prior to use. Another study (Tergney and Bolton, 2006), suggested that monitoring and trimming could reduce the incidence of faecal contamination as a result of both dehiding and evisceration by up to 50%, but only if the anatomical site of contamination was related to a causative operation and preventative corrective action was applied. In countries where carcass decontamination is practiced, the process is not applied until official inspection has determined absence of visible contamination on the carcass (Sofos, 2005).

3.3.2. Weaknesses of *post-mortem* inspection

The majority of gross abnormalities detected by the macroscopic organoleptic *post-mortem* examination of bovine carcasses are of animal health and/or meat quality relevance, and do not pose a serious threat to public health (Berends et al., 1993; DAFC, 2011; Hathaway and McKenzie, 1989). These include, for example, abnormalities that are caused by non-zoonotic agents (e.g. pneumonia/bronchopneumonia, parasites in bronchi), or by zoonotic agents that are not transmissible *via* the meat-borne route (e.g. *Echinococcus*, liver fluke), or are metabolic/organic abnormalities (e.g. cachexia, uraemia, obstructive icterus, DFD/PSE muscles). Therefore, it has been generally recognised that the actual effectiveness of the routine macroscopic *post-mortem* examination in detecting conditions/lesions relevant to public health and – particularly – human health hazards that meat-borne is limited (Blackmore, 1983; EFSA, 2005; Hathaway and McKenzie, 1989; Hathaway et al., 1987).

It is important to note that, as indicated above, the majority of patho-anatomical abnormalities found at *post-mortem* examination are not zoonotic hazards *per se*. Rather, the meat safety relevance of those abnormalities depends entirely on the nature of the causative agent involved in the condition, i.e. whether it is zoonotic or non-zoonotic, and if the former is capable of meat-borne transmission to the consumer. Therefore, only the causative agent can be considered as a meat safety hazard, and not the visible abnormality itself. Hence, the actual contribution of current macroscopic *post-mortem* examination to bovine meat safety is limited to those hazards that both cause macroscopically detectable abnormalities and are transmitted to consumers *via* the meat-borne route.

Among a number of zoonotic biological hazards that can be present in slaughtered bovine animals and be associated with macroscopically detectable conditions (Table 8), a large majority are considered as

not representing a public health threat via meat handling, preparation and consumption at household or food catering level.

Table 8: Zoonotic biological hazards in bovine animals, main association with macroscopic abnormalities and their detectability during current meat inspection practices.

Hazards	Priority category following ranking of hazards	Main association with macroscopic abnormalities	Method of macroscopic detection of abnormalities
Bacteria			
Actinobacillus ligneiressi	NA[1]: not meat-borne	granuloma of the tongue, enlarge lymph nodes of the head and neck	visual, incision
Aeromonas hydrophila	NA: not meat-borne	None	None
Anaplasma phagocytophilum	NA: not meat-borne	None (fever in acute stages)	None
Arcanobacterium pyogenes	NA: not meat-borne	abscesses, endocarditis, pneumonia	incision (abscesses in deep tissues, endocarditis); visual (pneumonia)
Arcobacter spp. (formerly mesophilic *Campylobacter* spp.)	NA: not meat-borne	None	None
Bacillus anthracis	Low	characteristic lesions, haemorrhages	visual
Bacillus cereus	NA: growth post-chill	None	None
Bartonella spp.	NA: not meat-borne	None (potentially endocarditis)	None
Borrelia burgdorferi	NA: not meat-borne	arthritis, skin lesions, encephalitis	visual
Brucella abortus	NA: not meat-borne	mastitis, signs of recent abortion	visual
Campylobacter spp. (thermophilic)	Low	None	None
Clostridium botulinum	NA: growth post-chill	None	None
Clostridium difficile	NA: growth post-chill	None	None
Clostridium perfringens	NA: growth post-chill	None	None
Corynebacterium spp.	NA: not meat-borne	mastitis	visual
Coxiella burnetii	NA: not meat-borne	mastitis	visual
Dermatophilus congolensis	NA: not meat-borne	dermatitis	visual
Fusobacterium necrophorum	NA: not meat-borne	abscesses, pneumonia, mastitis, metritis	incision (abscesses in deep tissues); visual (others)
Pathogenic VTEC	**High**	**None**	**None**
ESBL/AmpC gene-carrying *E. coli*	Undetermined	None	None
Erysipelotrix rhusiopathiae	NA: not meat-borne	arthritis, endocarditis, abscesses	visual
Leptospira hardjo	NA: not meat-borne	nephritis, icterus, mastitis	visual
Listeria monocytogenes	NA: growth post-chill	None	None
Mannheimia haemolytica	NA: not meat-borne	pneumonia	visual

Hazards	Priority category following ranking of hazards	Main association with macroscopic abnormalities	Method of macroscopic detection of abnormalities
Mycobacterium avium subsp. *avium*	NA: not meat-borne	caseous necrosis of lymph nodes, granulomas	incision
Mycobacterium avium subsp. *paratuberculosis*	NA: not meat-borne	characteristic thickening of intestinal wall	incision
Mycobacterium bovis	NA: not meat-borne	caseous necrosis of lymph nodes, granulomas	incision
Mycoplasma bovis	NA: not meat-borne	mastitis	visual
Pasturella multocida	NA: not meat-borne	pneumonia	visual
Salmonella spp.	**High**	**None**	**None**
Staphylococcus aureus	NA: growth post-chill	mastitis, nephritis, arthritis, abscesses	incision (abscesses in deep tissues); visual (others)
Streptococcus zooepidermicus	NA: not meat-borne	mastitis, nephritis, arthritis, hepatitis, endocarditis, abscesses	incision (endocarditis); visual (others)
Yersinia enterocolitica	NA: not meat-borne	None	None
Yersinia pseudotuberculosis	NA: not meat-borne	enteritis	visual
Viruses			
Bovine papilloma virus	NA: not meat-borne	papilloma lesions in skin and mucosa	visual
Encephalitis virus (TBEV from family Flaviridae)	NA: not meat-borne	behavioural (encephalitis)	visual
Lyssavirus (rabies)	NA: not meat-borne	behavioural (encephalitis)	visual
Parapox virus (pseudocowpox)	NA: not meat-borne	characteristic skin lesions	visual
Parasites			
Cryptosporidium parvum	NA: not meat-borne	None	None
Dicrocoelium dendriticum	NA: not meat-borne	invasion of bile ducts	incision
Echinococcus granulosus	NA: not meat-borne	hydatid cysts in liver, lungs, other organs	visual, palpation, incision
Fasciola hepatica	NA: not meat-borne	invasion of bile ducts	incision
Giardia duodenalis	NA: not meat-borne	None	None
Sarcocystis hominis	Low	none (sometimes eosinophilic myositis can be detected)	None
Taenia saginata cysticercus	Low	cysts in muscles (especially masseters, heart)	visual, incision

Hazards	Priority category following ranking of hazards	Main association with macroscopic abnormalities	Method of macroscopic detection of abnormalities
Toxoplasma gondii	Undetermined	None	None
Fungi			
Trichophytum verrucosum	NA: not meat-borne	dermatitis	visual

[1]NA = not applicable

For zoonotic hazards, the main contribution of current meat inspection is to animal health, rather than to human health via food/meat consumption. *T. saginata* cysticercosis and *S. aureus* are zoonotic hazards associated with macroscopically detectable conditions and representing human food-borne disease threats via meat consumption. However, and as discussed before, these hazards were ranked as of low-priority for meat inspection or the risk is associated with growth post-chill. Many studies report on the low sensitivity of meat inspection. Based on published studies, routine meat inspection was able to detect between 17 % and 71 % of the animals classified as infected using detailed dissection and slicing (see Appendix C for further details). Further, the indicated conditions may not necessarily contain *S. aureus* but be caused by other organisms; growth and toxin (which occurs at later meat chain stages) is required for this bacterium to cause food-borne intoxication; and strains causing the food-borne disease commonly originate from the human reservoir (EFSA, 2009b). All these issues markedly reduce the contribution of *post-mortem* inspection to meat safety.

A number of zoonotic biological hazards can be present in slaughtered cattle, but, because they are not associated with any macroscopically detectable condition, they remain undetectable by current *post-mortem* meat inspection (Table 8). These macroscopically undetectable hazards include the high-priority bovine meat-borne hazards identified previously: *Salmonella* spp. and pathogenic VTEC. The same applies to the low-priority hazard *Campylobacter* spp. (thermophilic), which is faecally excreted by healthy cattle and could consequently be transferred to carcasses during slaughter line operations. Their control relies mainly on prevention of faecal contamination and avoidance of cross-contamination of meat.

Therefore, with respect to the macroscopically undetectable biological hazards, current *post-mortem* inspection does not in practice contribute to the prevention of meat-borne disease in humans. Consequently, control measures for those hazards at the slaughterhouse, aimed at reducing the human meat-borne risks, are based on optimisation of process hygiene managed through good manufacturing practice (GMP)/good hygiene practice (GHP) and HACCP system principles ('owned' and implemented by the operator), rather than on official *post-mortem* meat inspection procedures *per se*. Furthermore, implementation of successful, where used, interventions against relevant microbial hazards in the meat chain up to and including the chilled carcass stage, such as air chilling, especially blast chilling, of carcasses (*Campylobacter*) or hide and/or carcass decontamination (*Salmonella* spp. and pathogenic VTEC) has mainly been initiated by the food industry, and has not been part of the current meat inspection system.

Manual handling of meat/organs of slaughtered bovine animals, this is palpation/incision conducted to detect macroscopic abnormalities, may lead to cross-contamination both within the same animal and between-animals at the slaughterline, with microorganisms (e.g. pathogenic VTEC, *Salmonella* spp.) present on the surfaces or inside tissues (e.g. in lymph nodes) (Samuel et al., 1980; Jankuloski et al., 2009; Brichta-Harhay et al., 2012). Further assessment on *post-mortem* meat inspection mediated microbial cross-contamination of bovine meat at slaughterhouses is presented below in Section 5.3. This is considered as a weakness of current *post-mortem* meat inspection because any cross-contamination is undesirable.

Other weaknesses of the current *post-mortem* examination system for bovine carcasses is the fact that, based on the findings, criteria used to judge meat/organs as unfit (inedible) for human consumption are not clearly specified in the context of the meat safety risk they pose. Namely, meat/organs can be declared unfit for human consumption for a variety of reasons, including: (i) ingestion of the meat will be harmful to humans; (ii) it may be harmful to humans, but via routes other than meat ingestion; (iii) it is not directly harmful to humans, but its removal from the food chain prevents the spread of animal diseases (e.g. foot and mouth disease); (iv) meat is of unacceptable quality (e.g. haemorrhages, intensive taint, etc); and (v) the meat is aesthetically unacceptable (e.g. foetus, non-zoonotic parasites, etc). A clearer specification of the reasons for declaring meat/organs unfit for human consumption would be beneficial for two reasons: it would help to focus meat inspection on public health goals (as

a priority) and it would aid identification of the tasks/situations where the controls should be part of the official meat inspection system or a component of the meat quality assurance system.

3.4. Conclusions and recommendations of the strengths and weaknesses of current meat inspection

The main elements of the current bovine meat inspection system include analysis of food chain information (FCI), *ante-mortem* examination of animals, and *post-mortem* examination of carcasses and organs. The assessment of the strengths and weaknesses of the current meat inspection was primarily focused on its contribution to the control of the identified high-priority bovine meat-borne biological hazards.

- Strengths of the current meat inspection methodology for the high-priority biological hazards are as follows:
  - In principle, adequate collection and proper utilisation of FCI can be useful and beneficial in *ante-* and/or *post-mortem* bovine meat inspection. FCI, used as part of *ante-mortem* inspection, provides information related to veterinary treatments and disease history during animal rearing and helps focus *ante-mortem* and/or *post-mortem* inspection on animal and public health concerns.
  - *Ante-mortem* and *post-mortem* inspection of bovine animals and carcasses enable detection of visible abnormalities, providing important benefits in monitoring animal health and welfare.
  - *Ante-mortem* inspection of bovine animals enables animal identification for traceability, and can be used to verify FCI given by the farmer and to provide feedback to producers on problems detected, but usually for issues not related to public health. *Ante-mortem* visual examination detects bovine animals with diarrhoea as well as visible faecal contamination that may be associated with increased risk of microbial cross-contamination during slaughter.
  - *Post-mortem* inspection detects visual faecal contamination on dressed bovine carcasses that may indicate potential exposure to the identified high-priority bovine meat-borne hazards.
  - *Post-mortem* inspection can detect *T. saginata* cysticercus, which, however was categorised as low-priority at EU level.
- Weaknesses of the current meat inspection methodology for high-priority biological hazards are as follows:
  - Currently, FCI collection is not harmonised, is used only to a limited extent, and is not adequate to allow classification of bovine farms/herds in relation to potential presence of the identified high-priority bovine meat-borne biological hazards *Salmonella* spp. and pathogenic VTEC.
  - Current *ante-mortem* and *post-mortem* macroscopic inspection are not able to detect any of the identified high-priority bovine meat-borne biological hazards.
  - Judgement of the fitness of bovine meat for human consumption by current *post-mortem* inspection does not differentiate food safety aspects from meat quality aspects, prevention of animal diseases, and occupational hazards.
  - Manual handling of meat, including use of palpation/incision techniques, during *post-*

mortem inspection does not contribute to the detection of the identified high-priority bovine meat-borne hazards; in fact, it may increase and spread these hazards by cross-contamination.

4. Recommended inspection methods for hazards not addressed by current meat inspection

4.1. Introduction

As described earlier in this Scientific Opinion, the high-priority biological hazards associated with meat from bovine animals are pathogenic VTEC and *Salmonella* spp. Consequently, recommended inspection methods for these hazards are outlined below. For *Toxoplasma gondii* and ESBL/AmpC gene carrying *E. coli* the priority was carachterised as 'undetermined' and, hence, these hazards are not considered further in this Appendix.

Live bovine animals that faecally shed the high-priority bovine meat-borne hazards, pathogenic VTEC and/or *Salmonella* spp., usually do not show any visible symptoms, and carcass derived therefrom usually show no signs of contamination. Consequently, current macroscopic meat inspection of bovine animals neither targets these hazards nor is able to protect the consumer against them. Current EU legislation (Regulation (EC) No 2073/2005) requires testing of bovine carcasses for *Salmonella* spp. as part of process hygiene criteria (PHC), but this activity is not part of official meat inspection and is not conducted for the purpose of judging the safety of bovine carcass meat. Rather, *Salmonella* testing is conducted by the FBO, and only for the purpose of slaughterhouse process hygiene assessment (PHA) and HACCP verification. Therefore, neither pathogenic VTEC nor *Salmonella* spp. are specifically targeted by activities carried out as part of meat inspection of bovine animals. Thus, an improved meat safety assurance system should include appropriate control procedures for these two 'new hazards'. When developing the approach to efficiently control these 'new hazards' along the farm-to-chilled carcass chain of events, several key issues, indicated below, have to be taken into account.

On-farm and during animal transport and lairaging, bacterial hazards, including pathogenic VTEC and *Salmonella* spp., are faecally shed by bovine animals and further disseminated *via* various direct or indirect routes through cross-contamination. This ultimately results in contamination of carcasses with these hazards, and subsequent human exposure to them *via* bovine meat. Detection and quantification of these hazards in/on bovine animals and their carcasses at the slaughterhouse may be possible through sampling and laboratory testing, with associated limitations. The occurrence and levels of pathogenic VTEC and/or *Salmonella* spp. on chilled bovine carcasses are unpredictable and highly variable depending on various factors, including: (a) their occurrence in bovine animals before slaughter and the application and the effectiveness of related pre-slaughter control strategies; (b) the extent of direct and/or indirect faecal cross-contamination during slaughterline operations, which is affected by process hygiene; and (c) the effectiveness of possible interventions to reduce contamination on carcasses (e.g. carcass decontamination), if applied. Therefore, contamination control strategies need to be applied in order to reduce the presence of these hazards on bovine carcass meat.

In summary, traditional, including current, meat inspection of bovine animals aims to assure meat safety primarily based on the following: a) detection of macroscopically observable abnormalities (lesions) that may contain public or animal health hazards; and b) immediate, on-line elimination (e.g. excision and appropriate disposal of suspect tissue) of those abnormalities presumably containing the hazards. However, the high-priority hazards identified above (i.e. pathogenic VTEC, *Salmonella* spp.) cannot be associated with macroscopically detectable lesions. Further, their laboratory detection is impractical in/on each carcass individually. Therefore, an effective overall control of these 'new hazards' in/on bovine carcass meat is possible only through a more comprehensive system of 'meat safety assurance' combining a range of preventative measures and related controls – applied both at the farm and at the slaughterhouse in a longitudinally integrated approach. The generic framework for meat inspection of bovine animals to better control the identified high-priority hazards, similar to that presented in previous EFSA Opinions for other animal species (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011, 2012), and the elements of such a system are considered below.

4.2. Outline of the proposed generic integrated bovine meat safety assurance system for the 'new' high-priority hazards

4.2.1. General aspects

By definition, this document deals with bovine meat inspection that is executed at the slaughterhouse; hence, the slaughterhouse plays the main role and is centrally placed in the generic bovine meat safety assurance framework developed. The proposed framework also includes considerations related to the on-farm status of the bovine animals in respect to the main hazards at the time of their presentation for slaughter, as well as considerations of at-slaughterhouse measures aimed at ensuring adequate status of final carcasses in respect to these hazards. However, the framework does not deal with other controls of these hazards taking place before or after the slaughter stage (e.g. not with controls aimed at earlier prevention of infection of bovine animals with the hazards or controls aimed at elimination/reduction of the hazards at meat processing-distribution-preparation stages). Whilst some of those other controls may be useful and effective in the context of global bovine meat safety, they are outside the scope of this document.

In modern, longitudinally integrated food safety assurance systems, the main responsibility for meat safety is allocated to the FBO. For such a system to be effective, it is necessary that the main participants in the food chain are given clear and measurable targets and/or related criteria indicating what they should achieve in respect to particular hazard-food combinations at each main point. These are set by regulators as prevalence or levels of the target hazards and/or indicator microorganisms found in the food under consideration, which are to be met by FBO. This is also in accordance with the 'Food Safety Objectives' (FSOs) - driven concept introduced by Codex Alimentarius and the International Commission on Microbiological Specifications for Foods (CAC/ICMSF). The main elements of concepts based on targets/criteria for foods, outlined in the current EU food hygiene legislation and on CAC/FAO-WHO/ICMSF guidance documents, are described in more detail in a previous EFSA Scientific Opinion on microbiological criteria for foods (EFSA, 2007c).

In respect to a meat safety assurance system at slaughterhouses, including bovine slaughterhouses, there are three global aspects of controlling each relevant hazard: firstly, what has to be achieved at the end point (chilled carcass); and secondly and thirdly, whether the target to be achieved is determined by the hazard's load in/on incoming animals (on-farm situation) and the effectiveness of the slaughterhouse operation in reducing the load (slaughterhouse operation situation). All these three aspects have to be known to both producers and regulators. The role of these three aspects is described below.

4.2.2. Principles of high-priority hazard-related targets for chilled carcasses

Setting and using 'targets' for high-priority hazards (i.e. 'Performance Objectives' (POs) in the terminology of the CAC or of the ICMSF) at the end point of both the bovine slaughterhouse operation and the bovine meat inspection, the chilled carcass, is an integral part of an improved bovine meat safety assurance system. The use of specific hazard-based targets (i.e. pathogenic VTEC/*Salmonella* spp. related) for bovine chilled carcasses provides:

i. measurable and transparent goals for the slaughterhouse meat safety assurance system;

ii. information (as 'benchmarks') on what has to be achieved at earlier steps in the beef chain;

iii. depending on global FSOs and Appropriate Levels of Protection (ALOP), information on risk-reductions required at post-slaughterhouse steps of the beef chain;

iv. information used to assess consumer exposure to a hazard; and

v. measurable aims for bovine meat industry in the context of global pathogen reduction programmes.

For all these reasons, targets set for chilled carcasses need to be set for specific hazards and cannot be replaced by indicator microorganisms-based targets. This, however, may not be always practical (e.g. in very low-prevalence hazard situations). Therefore, proper functioning of a meat safety assurance system should rely not exclusively on hazard-based testing of the final carcass but on the general hygiene of the slaughtering process. This issue is discussed further in following paragraphs.

Current EU legislation includes a PHC for maximum acceptable prevalence levels of *Salmonella* spp. on bovine carcasses at the end of the slaughterline. This requirement is inherently flawed because *Salmonella* spp. occurrence on carcasses depends, not only on the process hygiene performance of a given slaughterhouse, but also on *Salmonella* spp. prevalence and levels on incoming animals. Hence, when slaughtering animal batches that are *Salmonella* free or in which the prevalence of *Salmonella* spp. is low, the PHC may be met even if actual process hygiene is unacceptable — and *vice versa*. On the other hand, the current EU *Salmonella* PHC is considered *partly* as a *Salmonella* spp. target to be achieved by slaughterhouses. The issue is that, according to current EU PHC, the hazard is measured on carcasses before chilling, whilst in a target-based concept the hazard should be measured on chilled carcasses (i.e. just before further dispatch of chilled carcasses to the bovine meat chain). The chilled carcass is better suited for the hazard-related target concept, as prevalence/levels of microbial hazards on carcasses may change during chilling and because the chilled carcass is most relevant for estimating the potential consumer exposure. Furthermore, the current *Salmonella*-related EU criteria for final (not chilled) bovine carcasses are not clearly linked with other *Salmonella*-related criteria/targets at preceding and/or subsequent steps of the bovine meat chain.

4.2.3. Principles of process hygiene assessment in slaughterhouses and their risk categorisation

Setting and using indicators/criteria for PHC in slaughterhouses (i.e. Performance Criteria (PC) in CAC/ICMSF terminology) is an integral part of the meat safety assurance system. Bovine slaughterhouses differ in respect to the final outcome, e.g. microbiological status of carcasses (Small et al., 2006), as they have different process hygiene performances or microbial risk-reduction capacities. This is because, even for the same-species, operations can vary considerably between individual slaughterhouse in terms of the hygienic characteristics of the technologies and the equipment used, the extent to which the procedures are standardised and documented, the technical knowledge of the operators, the level of food hygiene training and its application, and the motivation of staff and management. Consequently, any programme used to assess and control the actual effectiveness of a safety system needs to be based on risk classification of premises/operations (FAO and WHO, 1998; Motarjemi, 2000).

4.2.3.1. Process hygiene assessment role and methodology

Currently in the EU, Regulation (EC) No 2073/2005[13] establishes PHC which give guidance on, and are an indicator of, acceptable implementation of pre-requisite programmes GMP-GHP and HACCP-based systems to ensure hygienic functioning of slaughterhouse processes. It sets indicative microbial contamination values for carcasses above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law requirements. The maximum values are set for indicators of overall contamination (total viable count of bacteria (TVC)), indicators of contamination of enteric origin, and *Salmonella* spp. prevalence. However, as previously explained (EFSA, 2007c) the nature of the PHC is similar to that of so-called 'end-product' criteria because:

- the set contamination values are applicable only to the product at the end of the manufacturing

13 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Official Journal of the EU L 338, 22.12.2005, p. 1–26

process (final carcass); and

- they are not related to the (normally highly variable) initial contamination values of the raw materials at the individual operator level.

In other words, current EU-legislated PHC for slaughterhouses do not provide measures of the actual capacity of the process to reduce the incoming contamination; they only show the process outcomes. This is a significant weakness of the current EU-legislated PHC system relative to the need to microbiologically characterise the slaughterhouse process itself, and to provide a measure to be used for differentiation/classification of slaughterhouses based on the hygienic efficiency of their processes.

The shortcomings of using only final carcass-related microbiological criteria in the assessment of red meat (including bovine) slaughterhouse process hygiene were recognised earlier and characterisation of the process by analysing microbial loads at multiple stages of the process was advocated (Gill and Jones, 1997; Bolton et al., 2000). In addition, principles of a simplified approach, based on determining differences in specified indicator organisms (e.g. mean TVC and/or *Enterobacteriaceae* counts) between final carcasses and surfaces of corresponding incoming animals (post-slaughter but pre-skinning), has been suggested (Vivas-Alegre and Buncic, 2004; Blagojevic et al., 2011a). This would enable a more precise assessment of the capacity of each slaughterhouse process to reduce contamination, and a more reliable differentiation between slaughterhouses. However, although there is clearly a need for improvement, no single improved method for PHA of bovine slaughterhouses has been developed and standardised in the EU.

Unlike high-priority hazard-based targets that need to be set for chilled carcasses (end products of the slaughterhouse) and which are related to same-hazard targets set for other steps in the bovine meat chain, the slaughterhouse PHC do not need to be based on actual hazards (i.e. pathogenic VTEC and *Salmonella* spp.). This is due to practical difficulties caused by the usually low prevalence/levels of these hazards in bovine animals and on their carcasses, the difficulties in quantification of hazards (e.g. methodology limitations, low and unpredicted prevalence and associated sampling limitations), and the requirement for more laborious handling in well equipped laboratories. Hence, PHC should be normally based on counts of selected indicator microorganism(s), which is/are much better suited for use in PHA, than pathogenic microorganisms (Blagojevic et al., 2011a; Bolton et al., 2000; Koutsoumanis and Sofos, 2004). However, it is important to keep in mind that indicator organism-based PHC are potentially risk-based, process failure-based or trend analysis-based, but not actual hazard-based.

For PHA harmonisation, it is important to consistently use: a) the same indicator(s); and b) a testing frequency proportionate to the risk. Because both pathogenic VTEC and *Salmonella* spp. are enteric organisms, common gut commensal organisms – such as *E. coli* or *Enterobacteriaceae* – are widely considered as the most appropriate indicator organisms. Currently, bovine slaughterhouse PHC use *E. coli* counts of carcasses in USA, and *Enterobacteriaceae* counts of carcasses in the EU. The use of *E. coli* has the advantage that the organism reflects faecal contamination more specifically than *Enterobacteriaceae*, but it has the disadvantage that its prevalence/counts is/are generally lower than those of *Enterobacteriaceae* (which may cause problems in results/trend analysis - associated with a high number of 'zero' counts). Regardless of which indicator organism is chosen, the PHA-related testing frequency should reflect the risk status of the slaughterhouse, both in terms of its performance pre-history (e.g. the longer-term trend) and its human exposure potential (e.g. the number of animals slaughtered).

It should be noted that: (a) further work on development of optimal sampling and analytical methodology is required; and (b) the final selection of the chosen method and criteria is a risk management (regulatory) responsibility, as it involves consideration not only of scientific aspects, but also of feasibility, practicality, costs, laboratory requirements and availability, and intended purpose of the results.

4.2.3.2. Process hygiene-based differentiation of bovine slaughterhouses

Current EU regulation differentiates slaughterhouses into 'acceptably' or 'unacceptably' performing based on PHC. However, as this differentiation is based solely on testing of finished carcasses, it does not differentiate slaughterhouses in terms of process effectiveness; only on the status of end products (carcasses). A more in-depth differentiation, even within each of the above two global categories of slaughterhouses, could be possible through the use of improved PHA methodology and proper indicators. The main guiding principle (Koutsoumanis and Sofos, 2004) in slaughterhouse process hygiene differentiation is that the PHC used need to address initial levels of a hazard and their reduction during the production process. The main question to consider when developing PHC for slaughterhouses is whether they should be linked to individual stages of the process (e.g. reduction of occurrence/level of indicator organisms or hazards at a selected one or more than one specific steps along the slaughterline) or only related to the starting and the end point of the process (e.g. reduction of the occurrence/level in/on the final carcass meat compared to that in/on incoming animals).

Summarising, it is clear that an improved methodology, as well as criteria for actual microbiological characterisation of process hygiene in bovine slaughterhouses, are needed. No such methodology has been developed, accepted and standardised in the EU to date. More accurate information of this type would enable differentiation ('risk categorisation') of slaughterhouses relative to their capacity to potentially (as there is no clear evidence of quantitative correlation between indicator organisms and those hazards) reduce pathogenic VTEC and *Salmonella* spp. This, in turn, would enable different risk management options for various risk categories of slaughterhouses, including:

- optimised matching of *Salmonella* spp. and pathogenic VTEC risk categories of bovine animals with the risk management capacity of slaughterhouses, including guidance as to whether/where additional *Salmonella* spp. and/or pathogenic VTEC risk-reducing interventions should be applied (e.g. carcass decontamination step);

- more stringent requirements for monitoring/verification/auditing programmes for higher-risk slaughterhouses;

- more reliable feed-back information on roots of problems with *Salmonella* spp. and/or pathogenic VTEC on bovine meat to farm of origin; and

- clearer identification of slaughterhouses where improvement of technologies and processes is needed.

The PHC are considered to be a key component of the proposed meat safety assurance system. In that context, consideration would need to be given to issues such as the related sampling plans and microbiological methods to be employed, and the need for regulatory auditing of the PHA (which may include record verification and if necessary microbial testing).

4.2.4. Principles of priority hazard-related targets for incoming bovine animals

Targets set for a given hazard in bovine chilled carcasses at slaughterhouses can be used as guides in setting corresponding aims to be achieved by farms delivering bovine animals. Achievement of the ultimate target (on chilled carcasses) is determined not only by the effectiveness of the slaughterhouse operations in reducing the load (slaughterhouse operation situation), but also by the hazard load in/on incoming animals (i.e. on-farm situation). For example, when the process hygiene performance (i.e. hazard reduction capacity) of a given slaughterhouse is consistent, the final hazard-related status of finished carcasses will vary only between animal batches carrying significantly different loads of the hazard.

4.2.4.1. Risk categorisation of incoming bovine animals

Knowledge of likely loads (prevalence/levels targets) of the high-priority hazards, pathogenic VTEC and *Salmonella* spp., present in/on incoming bovine animals for slaughter is necessary for selecting changes in the slaughterhouse operation that could ensure achievement of targets set for chilled carcasses. Such knowledge can be obtained through the use of on-farm hazard monitoring and/or historical data from at-slaughterhouse hazard testing of slaughtered animals of the same origin.

Risk categorisation of incoming animals could also include information on visual cleanliness of bovine animals (currently assessed at *ante-mortem* inspection), as it may be relevant for *Salmonella* spp. and pathogenic VTEC related risks. The degree of visual cleanliness of the hide cannot be used as the only indicator of absence or presence of the two hazards in bovine animals. Nevertheless, for batches of bovine animals originating from *Salmonella* spp. or pathogenic VTEC positive farms, it could be assumed that dirtier animals (those more contaminated with faecal material) could present a higher risk for cross-contamination of the slaughterline environment, including the carcasses.

An additional factor taken into account when considering risk differentiation of animals is whether they are coming from so-called 'integrated' or from 'non-integrated' farming systems. Integrated animal production systems were defined by expert groups (SCVMPH, 2000a, 2001) and were subsequently included in EU legislation (Regulation (EC) No 854/2004). The criteria used for differentiation include two main groups: (a) they must operate under Good Farming Practices (GFP), GHP and respect the fundamentals of HACCP philosophy; and (b) they must have quality assurance systems in place to ensure control over, and availability of information about, a number of issues including: (i) animal identification (movement, traceability); (ii) epidemiological intelligence (data from herd health plans, monitoring/surveillance, medicines and veterinary treatments); (iii) farm animal management and QA (welfare; housing and handling facilities; feed composition, storage and use; biosecurity); and (iv) environment and hygiene management. Because 'integrated' farming systems are generally expected to operate higher standards, using more standardised, controlled and documented practices, bovine animals coming from those systems are considered to be in better condition and general health. This may imply that they are generally less risky in the context of bovine meat safety hazards than those from 'non-integrated' systems. Although detailed information on direct relationship between condition/general health and pathogenic VTEC/*Salmonella* spp. carriage in bovine animals is lacking, it can at least be presumed that pathogenic VTEC/*Salmonella* spp. risk factors are likely better controlled on farms with quality assured GFP (integrated system) and that this would likely reduce the corresponding risk associated with resultant animals.

Based on the pre-slaughter information indicated above, incoming bovine animals can be risk-differentiated (risk categorised) at farm/herd level relative to the identified priority hazards. Such categorisation could enable informed decision making as to the choice of the appropriate slaughterhouse based on its risk management capacity (where possible, taking marketing and animal welfare considerations into account), including considerations as to whether/where additional pathogenic VTEC/*Salmonella* spp. risk-reducing interventions could be applied (e.g. carcass decontamination step).

Overall, the final risk categorisation of incoming bovine animals can be based primarily on the following:

a) which and how many on-farm pathogenic VTEC/*Salmonella* spp. risk factors exist on a given farm;

b) which and how effective control measures targeting the risk factors are implemented on that farm; and

c) are these hazards actually present, and how prevalent they are, in the bovine animals.

As far as the first two points above are concerned, information on the main relative parameters could be obtained through auditing farms for relevant practices. In respect of the third point, the main parameters could be obtained through testing of animals for the hazards (on-farm testing and/or historical data from at-slaughterhouse testing). In the case of *Salmonella* spp., testing may be based on serological methods (e.g. blood/meat juice samples) which would indicate previous bovine exposure to the hazard but not its current presence. In the case of both *Salmonella* spp. and pathogenic VTEC, testing also can be based on microbiological methods (e.g. faeces, hide, carcasses), which would indicate actual presence of the hazard but not when/where the infection/contamination could have occurred. In theory, an additional factor could be also used for pathogenic VTEC risk categorisation of incoming bovine animals: identification of 'super-shedding' animals (see Annex B). However, for that, viable pathogenic VTEC cells would have to be determined in faeces before slaughter, which would require more sophisticated/laborious laboratory conditions; hence this theoretical approach has yet to be proven in a commercial environment (AHVLA, 2013). Taking all the above into account, it seems logical that risk categorisation of incoming bovine animals is based not on a single parameter, but rather on more complex information obtained through combination of various parameters. The appropriate parameters and approaches to combine them for the purpose of risk ranking of bovine animals is further elaborated in the related Scientific Report of EFSA (EFSA,2013).

The information that reflects the history of the farm/herd can be used to:

- differentiate ('risk categorise') farms/herds of bovine animals according to the risk they pose in respect of the main bovine meat-borne hazards (pathogenic VTEC and *Salmonella* spp.);
- apply strategies, based on herd health programmes, GHP and GFP, to reduce the prevalence of herds carrying the hazards; and
- optimise, to the degree that may be practical, the matching of *Salmonella* spp. and pathogenic VTEC risk categories of bovine animals with the risk management capacity of slaughterhouses, including considerations of whether/where additional pathogenic VTEC/*Salmonella* spp. risk-reducing interventions should be applied (e.g. carcass decontamination step).

4.2.5. Principles of use of Harmonised Epidemiological Indicators in the proposed generic bovine meat (carcass) assurance system

In order to avoid confusion resulting from the mentioned differences in the terminology used in the EU and the CAC/ICMSF documents, only the following terms are used in the remainder of this Appendix: (a) 'target' when referring to what has to be achieved in respect to each hazard in/on final, chilled bovine carcasses or incoming animals; and (b) 'process hygiene indicator/criteria' when referring to the effectiveness of slaughterhouse operations in preventing/reducing carcass/meat contamination.

It is important to keep in mind that, in this Appendix, only the principles of setting and using targets/criteria for bovine chilled carcasses, bovine slaughterhouse process hygiene, and incoming bovine animals are outlined. Further details on exact points along the farm-to-chilled carcass chain of events where the targets/criteria are to be applied, as well as on related sampling-examination methodology for each hazard, are outlined through HEI as described in a separate EFSA Scientific Report (EFSA, 2013). Therefore, this Scientific Opinion and the mentioned EFSA Scientific Report should be used in combination. Also, it is important to note that the actual hazard's prevalence/level numerical values related to each HEI are outside the scope of both these documents and remain to be set by the risk managers.

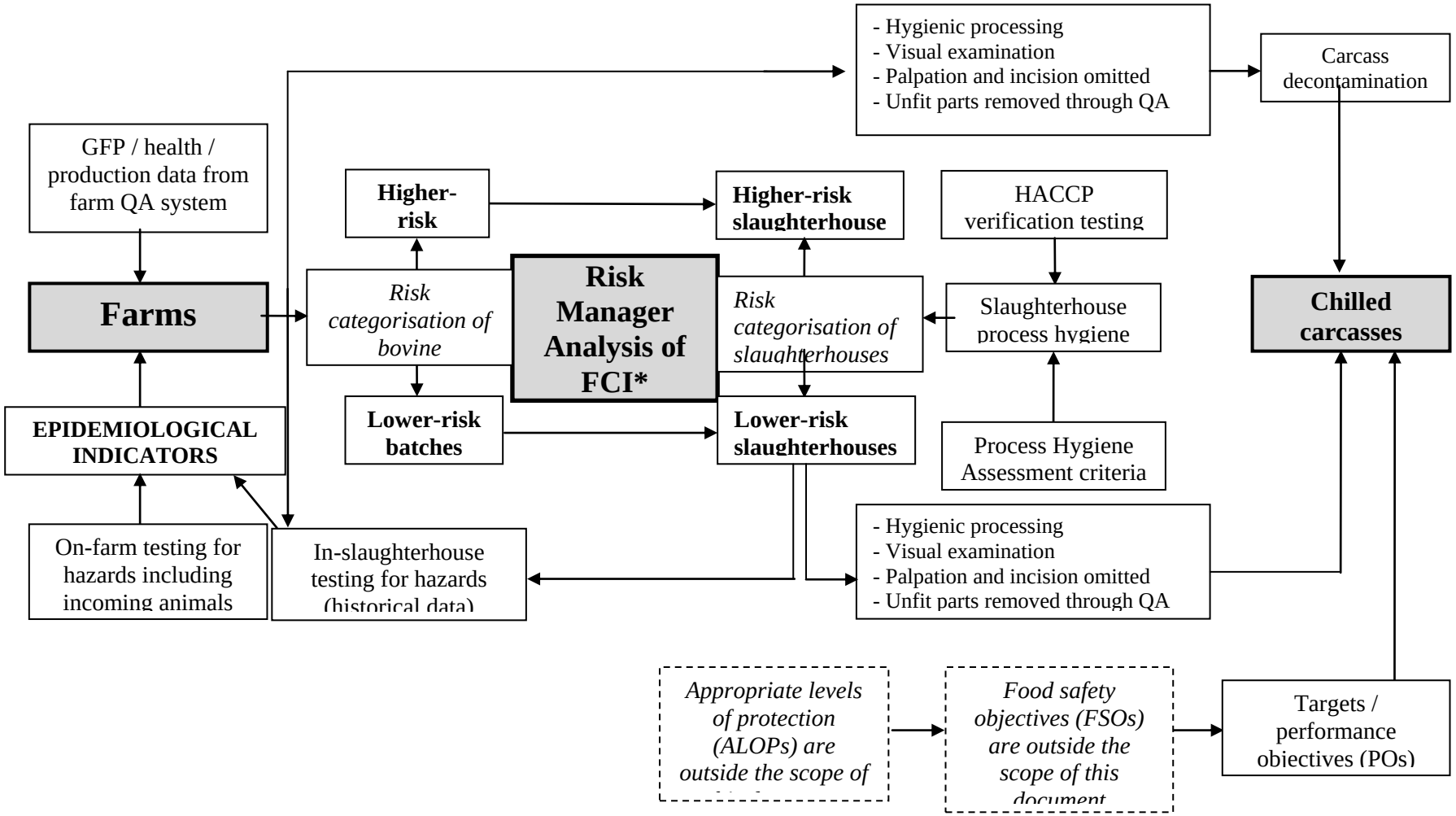
EU targets to be reached at the national level in bovine animals and/or on bovine carcasses are not in place for any of the high-priority hazards identified in this Opinion, in contrast to those already in

place for poultry (EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2012).

Targets should be risk-based, and can be derived from results of EU-wide baseline surveys. The following steps for setting targets and implementing monitoring programmes can be identified:

- conduct an EU-wide baseline survey at farm/herd and/or carcass level;
- set targets at carcass level;
- set targets at the farm/herd level, if appropriate; and
- decide on the design of monitoring programmes to verify whether the targets are met.

The outline of the proposed food safety assurance system for the high-priority hazards, showing an example of alternative risk management options, is presented in Figure 2. In the accompanying Scientific Report of EFSA (EFSA, 2013), a number of HEIs are proposed for the high-priority hazards at different stages of the farm-to-slaughterhouse chain of events.



*This is an example of alternatives that the risk manager may select

Figure 2: Main elements of a generic example of bovine meat (carcass) safety assurance system with respect to *Salmonella* spp. and pathogenic VTEC.

4.2.6. Principles of use of improved FCI in the proposed generic bovine meat (carcass) safety assurance system

As indicated above, it is envisaged that monitoring of the main hazards at the farm level by use of HEIs could serve to risk-differentiate herds of bovine animals. This would inform the FCI, which could enable improved risk-based management at the slaughterhouse. Likewise, HEIs at the slaughterhouse level can form the basis for risk differentiation of slaughterhouses, which again can be used for risk management purposes, e.g. by diverting high-risk herds/batches to slaughterhouses or specific slaughter lines with appropriate slaughter process hygiene performance.

As indicated above, in respect to each of the priority bovine meat-borne hazards identified (*Salmonella* spp. and pathogenic VTEC), risk categorisation of herds/batches of bovine animals based on use of historical testing data and application of hazard-specific harmonised epidemiological criteria should be included and considered within the FCI. Furthermore, in the case of hazards for which the ultimate risk reduction on carcasses also depends on the process hygiene performance of slaughterhouses (i.e. *Salmonella* spp. and pathogenic VTEC), it is necessary that such historical data be also considered within the FCI. In addition, in the case of hazards for which the ultimate risk reduction may depend also on hazard-inactivation treatments at the slaughterhouse (e.g. surface decontamination for bacterial hazards; heating/freezing treatments for parasitic hazards), it is necessary that historical data on validation/verification of those treatments be also considered within the FCI. Therefore, the FCI needs to include both animal farm/herd- and slaughterhouse-related information relevant for each high-priority hazard, and both of these elements are to be used in combination by the risk manager in a way that should maximise the ultimate risk reduction achieved on chilled carcasses. Current meat inspection of bovine animals does not utilise FCI in such a way relative to *Salmonella* spp. and pathogenic *E. coli*; hence the FCI element of the bovine meat (carcass) safety assurance system needs to be improved accordingly.

In the future, when more comprehensive and complete FCI would be available and used in a more systematic way, an informed decision can be made on how to balance the risk category of the incoming bovine animals and the risk category of the slaughterhouse operation - so that the targets for hazards on chilled carcasses are achieved. Such decisions are to be made for each specific situation, depending on the specific FCI. Examples of possible scenarios include, but are not limited to, the following:

- slaughtering of lower-risk bovine animal batches (with very low prevalence/levels of *Salmonella* spp. and/or pathogenic VTEC) in low-risk slaughterhouses (with good process hygiene i.e. risk reduction capacity) where only application of hygienic and HACCP-based slaughter-dressing processes may be sufficient to achieve established targets for chilled carcasses.
- slaughtering of higher-risk bovine batches (with certain prevalence/levels of *Salmonella* spp. and/or pathogenic VTEC) in slaughterhouses where hygienic and HACCP-based slaughter-dressing processes may not be sufficient, and thus additional risk-reduction interventions are implemented (e.g. decontamination) as necessary to meet established targets for chilled carcasses.

Deciding which of various possible scenarios is to be applied in a specific animal batch-slaughterhouse situation is a risk management responsibility. It requires defined criteria for each hazard, separating lower and higher risk categories of both batches and slaughterhouse processes, to be defined. The principles of setting/application of these criteria are indicated above, their more operational aspects (sampling/testing methodologies) are further elaborated in the parallel EFSA Report (EFSA, 2013), and future definition of numerical values for each criterion are a regulatory responsibility.

From a practical perspective, FCI analysis and related decision-making is a complex task, as in some situations the same batch of incoming bovine animals may represent different risk categories relative to different hazards. For example, incoming batches of animals may pose a lower risk of *Salmonella* spp. but a higher risk of pathogenic VTEC, or the opposite, or the two risks may be similar. The risk manager will have to select a scenario generating the overall best contribution to public health. This clearly indicates that the risk manager should be playing a central role in future bovine meat (carcass) safety assurance systems, and thus must have necessary training, skills and competence.

Furthermore, batches of bovine animals of unknown risk category for a given hazard should be regarded as of high risk. Although best practices require that batches are not mixed, should this occur, the mixing of batches of high risk category with those of low risk animals should be considered as resulting in a batch of overall high risk. It is recommended that all parties involved in the proposed integrated bovine meat safety assurance system, including official veterinarians, official auxiliaries, slaughterhouse staff and farmers, should be trained in the skills required for operating the new system.

4.3. Controls ('inspection methods') for *Salmonella* spp. and pathogenic VTEC

4.3.1. Options for control at farm level

Control of pathogenic VTEC and *Salmonella* spp. at farm level is complicated by the fact that bovine animals are asymptomatic carriers of these organisms and without an active monitoring programme there is no way of knowing which animals are carriers and/or shedding at any given time. Control activities must therefore be directed at the herd level. Furthermore, the pathogens may survive for extended periods in a range of faecal, slurry, soil and water environments encountered on bovine animal farms (Bolton et al., 1999; Himathongkham et al., 1999; Besser et al., 2001; McGee et al., 2001; Islam et al., 2004; Hutchison et al., 2005; Fremaux et al., 2008; O'Neill et al., 2011; Bolton et al., 2012).

Although in-depth consideration of the on-farm risk factors and controls for pathogenic VTEC and *Salmonella* spp. would need to be both pathogen- and animal species-specific, the main principles of and measures for their on-farm control are common and relatively universally applicable. These are summarised in Figure 3.

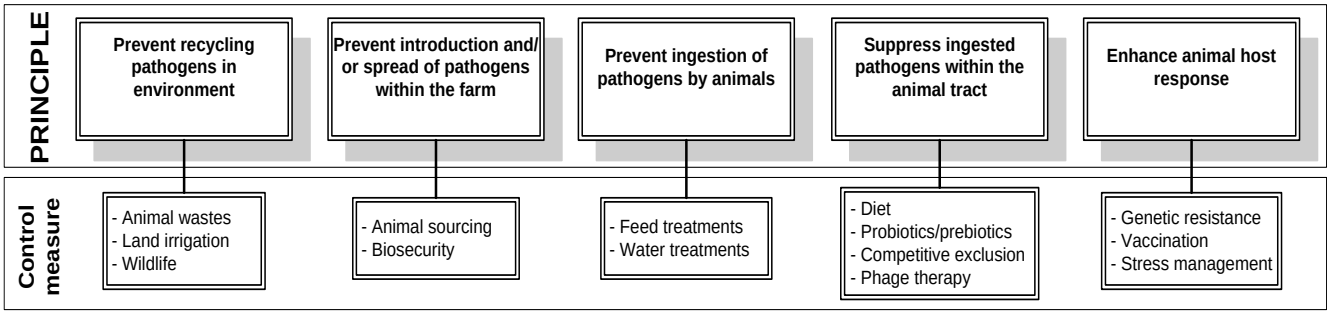


Figure 3: Main principles and control measures for meat safety at the pre-harvest phase (modified from Noerrung et al., 2009).

A range of GFP- and GHP-based measures to reduce these hazards on-farm exist, but presently none can ensure consistently and reliably total elimination of the hazards from bovine animals and farms/herds across the EU. General biosecurity (including avoidance of contact with other herds) and QA principles (e.g. welfare; housing, handling facilities and grazing areas; feed composition, storage and use; data recording) are important in this context. Experience from Finland, Norway and Sweden regarding *Salmonella* spp. shows that it is possible to control this agent at herd level based on the factors presented above including categorisation of herds/farms.; it is also important to state that the infection pressure is low in this region. For pathogenic VTEC, however, there are a number of

challenges that need to be overcome for this approach to be feasible, including the difficulties in identifying husbandry factors that can be used to classify farms according to pathogenic VTEC risk, the intermittent nature of shedding, and problems associated with the interpretation of pathogenic VTEC monitoring results due to difficulties in correctly identifying pathogenic VTEC. Further research is needed in order to better understand the efficiency of on-farm available practices for control and reduction of these hazards.

As a consequence, coordinated use of combinations of multiple control options may to reduce these hazards on-farm. Details on practices that could be used for controlling these hazards at farm level, based on published reviews (Noerrung et al., 2009; SAC and UoG, 2011), are briefly presented in Annex B. Control practices can be targeted at different levels, including the following:

- Preventing the recycling of the pathogens in the environment.
- Preventing the introduction and/or spreading of pathogens within the farm.
- Preventing the ingestion of the pathogens by the animals.
- Suppressing the pathogens within the animal gastro-intestinal tract.
- Enhancing the animal host response against the pathogens.
- Preventing and/or reducing pathogen spreading during transport.

There are significant differences between farms/herds of bovine animals in farming practices, risk factors, and controls used for *Salmonella* spp. and pathogenic VTEC and, hence, potentially and in the contamination status of bovine animals sent for slaughter. This indicates that it should be possible to risk differentiate (categorise) bovine animals sent to slaughter for *Salmonella* spp. / pathogenic VTEC through use of FCI, based on historical data on the farms/herds, and information gathered through application of appropriate HEIs. Research on the optimal ways of using the collected FCI data for risk categorisation of farms/herds of bovine animals, as well as approaches for assessing the public health benefits (e.g. by means of source attribution methods) is required.

It is recommended that in regions where *Salmonella* spp. is not controlled at farm level, preventive measures should be implemented to avoid its introduction in negative holdings or regions.

4.3.2. Options for control at slaughterhouse level

In the context of this Opinion, the at-slaughterhouse element of the bovine meat safety assurance system includes all the steps and operations occurring within the bovine slaughtering establishments between the unloading of animals on arrival and the final chilled carcass. To minimise cross-contamination of bovine carcasses in the slaughterhouse, all these steps and operations must be properly controlled.

A review of the different measures and controls that can be taken or applied in the slaughterhouse for controlling and/or reducing cross-contamination and spreading of the hazards is presented in Annex C. The different control options available could be summarised and categorised as follows:

- Related to slaughterhouse operation-mediated cross-contamination. This would include:
  - Assessment of visual cleanliness of animals.
  - Prevention/reduction of pathogen spreading during lairaging.

  - Hygienic dressing of slaughtered bovine animals.
  - Antimicrobial decontamination treatments of bovine carcasses.
  - Carcass chilling.
  - General management of microbial risks within slaughterhouse operations.
- Related to meat inspection-mediated cross-contamination.

Following the proposed bovine meat safety assurance system, the proposed risk categorisation of slaughterhouses should be based on trends in data derived from PHA and from HACCP programmes. Improvement of slaughter hygiene should be sought in slaughterhouses with historically unsatisfactory performance through technological and managerial interventions.

It is well established that the main sources of at-slaughterhouse bovine carcass contamination with pathogenic VTEC and *Salmonella* spp. are hides and intestinal contents. Contamination of carcasses with these hazards occurs via numerous routes, including direct exposure during dehiding and evisceration and indirect contamination through contaminated equipment, tools, knives, aerosols, and manual handling during *post-mortem* inspection.

Bovine slaughterhouse operation-mediated meat contamination and cross-contamination can be reduced through implementation of a range of general (GMP/GHP) and more specifically defined (HACCP) measures, whilst *post-mortem* inspection-mediated cross-contamination could be minimised by omission of related palpation/incision activities.

High risk herds or animal batches could be subjected to additional control measures such as logistic slaughter, reduced line speed slaughter, and decontamination interventions, or might be directed to slaughterhouses which have demonstrated an enhanced ability to control carcass contamination. In extreme cases, meat derived from the carcasses of high risk bovine animals may be used only for heat processed or cooked products. Batches of unknown risk category for a given hazard, or mixed batches that include animals of unknown or high risk category for a given hazard should be handled as of high risk.

There are significant differences among bovine slaughterhouses in slaughter technologies, effectiveness of their hygienic procedures, speed of slaughter, facility design, sanitation effectiveness and worker practices; each of these aspects alone and in combination can affect the pathogenic VTEC/*Salmonella* spp. status of the final carcasses. Hence, the overall process hygiene performance differs among slaughterhouses, and this, in turn, means that slaughterhouses can be differentiated or placed in different categorises. Collection of baseline data and development of approaches for slaughterhouse PHA through the use of indicator organisms, and the use of such results for risk categorisation of slaughterhouses is recommended.

4.4. Conclusions and recommendations on inspection methods for new hazards

Since none of the bovine meat-borne biological hazards categorised as of high-priority can be detected by traditional macroscopic meat inspection, other approaches are necessary to control these hazards. This can be best achieved using FCI and risk-based controls along the farm to chilled bovine carcass continuum.

An integrated bovine meat safety assurance system has been outlined and includes the need for clear and measurable high-priority meat-borne hazard-based EU targets (hazard prevalence and/or concentration) to be achieved by Food Business Operators (FBOs) in/on bovine carcasses and, when appropriate, in bovine farms/herds.

Risk-based targets derived from harmonised monitoring are not yet available for the bovine meat-borne biological hazards categorised as of high-priority for meat inspection (i.e. *Salmonella* spp. and pathogenic VTEC).

An important element of an integrated bovine meat safety assurance system should be risk categorisation of farms/herds of bovine animals based on farm descriptors and historical data as well as herd-specific information, including monitoring of Harmonised Epidemiological Indicators (HEI) as described in the related Scientific Report of EFSA (EFSA, 2013).

Significant differences exist among bovine farms/herds in farming practices, risk factors and controls used in respect to *Salmonella* spp. and pathogenic VTEC, and thus potentially in the corresponding status of bovine animal batches sent to slaughter. This indicates that it should be possible to risk categorise bovine animal batches sent to slaughter for *Salmonella* spp. and pathogenic VTEC through use of FCI, based on farm/herd historical data, and information gathered through application of appropriate HEI.

Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments and from Hazard Analysis Critical Control Point programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

High-risk animal batches or herds should be subjected to additional slaughter hygiene control measures and possibly complemented with decontamination treatments, or might be directed to slaughterhouses having demonstrated an enhanced ability to control carcass contamination. Where necessary, meat derived from carcasses of high risk animals may be used only for heat processed or cooked products. Animal batches of unknown risk category for a given hazard or mixed batches that include animals of unknown or high risk category for a given hazard should be handled as of high risk.

All parties involved in the proposed integrated meat safety assurance system should be trained in the skills required.

Research is needed on optimal ways of using the collected FCI data for risk categorisation of bovine farms/herds, as well as approaches for assessing public health benefits (e.g. by means of source attribution methods).

For risk categorisation of slaughterhouses, baseline data collection and development of approaches for slaughterhouse Process Hygiene Assessment through use of indicator organisms are needed.

In regions where *Salmonella* spp. is not controlled at farm level, preventive measures should be implemented in order to avoid its introduction in negative holdings or regions.

5. Recommended adaptation of inspection methods to provide an equivalent protection for current hazards

5.1. Food chain information

Currently in the EU, the use of FCI for food safety enhancement purposes is limited in bovine animals, except for animal identification used mainly for BSE control measures. Despite its limitations, FCI could constitute a valuable tool for risk management decisions and could be used for risk categorisation of animal lots/batches. To improve this aspect, the system needs to be further developed to include additional information important for food safety, including definition of appropriate and standardised indicators for the high-priority hazards identified as targets of a modernised meat inspection system.

An important element of an integrated food safety assurance system is risk categorisation of herds of bovine animals based on the use of farm descriptors and historical data in addition to herd-specific information, including the results of harmonised monitoring. Farm-related data could be provided through farm audits using HEI to assess the risk-associated and protective factors for the herds related to the target hazards (EFSA, 2013).

5.2. *Ante-mortem* inspection

Meat for human consumption should be derived from the slaughter of healthy animals. This Appendix is focused on control of biological hazards associated with the handling, preparation and consumption of bovine meat, as they exist on chilled carcasses at slaughterhouse.

Inspection of bovine animals on arrival at the slaughterhouse is an important regulatory procedure that helps to enforce acceptable standards for bovine transport and handling that might indirectly contribute to maintenance of operating procedures that minimise the general risk associated with unhygienic and stressful management of food animals. Stress is considered as an important factor in the excretion and spread of food-borne zoonotic pathogens such as *Salmonella* spp. and pathogenic VTEC by animals during and after transport to slaughter. Thus, animal handling and inspection procedures resulting in prevention of unnecessary stress are likely to be beneficial.

Ante mortem inspection does not directly contribute to the detection of the meat-borne hazards identified as of high-priority at present, but it can help to detect conditions such as diarrhoea and/or excessive faecal contamination that might indicate presence of the identified pathogens. Bovine animals that are excessively dirty on arrival could be externally contaminated with bacterial pathogens that may subsequently contaminate the slaughter plant and pose a higher risk of contamination of the carcass during dressing.

Findings at the slaughterhouse, that reveal recurring problems with heavily contaminated bovine animals or batches that are routinely positive for the high-priority bovine meat-borne hazards identified as targets of inspection, should be shared with the farm operator to enable appropriate action to be taken. On farm *ante-mortem* inspection could also be implemented (as is currently the case in some MSs) in the case of farms experiencing such recurring problems, as identified through the FCI. A frequent or constant supply of dirty bovine animals by specific individual producers could be the cause of advisory feedback or, for example, penalties that could be lifted after improvements are made.

In conclusion, *ante-mortem* inspection does not directly contribute to the detection of the high-priority meat-borne hazards identified, but it can help to detect bovine animals that are heavily contaminated with faeces or with diarrhoea. Taking this into consideration, and given that current *ante-mortem* inspection methods do not increase the microbiological risk to public health, no adaptations to the existing visual *ante-mortem* inspection procedures are found to be required.

5.3. *Post-mortem* inspection

According to current EU legislation (Reg. (EC) No 854/2004), routine macroscopic *post-mortem* inspection of bovine animals includes visual examination of the skin, carcass (including skin, joints, pleura/peritoneum, cut carcass muscles), head, liver, lungs, heart, kidneys, spleen and all other visible organs/tissues of slaughtered bovine animals for signs of abnormalities. Furthermore, as prescribed in the legislation, certain organs/tissues (e.g. mastication muscles, heart, lungs, liver, specified lymph nodes) are also routinely examined by palpation and/or incision. Subsequently, based on the inspection findings, the fitness of each bovine carcass and corresponding offal for human consumption is judged, followed by either passing the meat/offal to chilling and subsequently in the food chain, or immediate partial or complete condemnation. In cases where detected abnormalities/conditions cannot be properly diagnosed on the slaughterline, additional and more detailed macroscopic examination is applied, which may also include sampling for laboratory testing. In the latter case, judgement of fitness of the slaughtered animal for consumption is postponed until the laboratory results are obtained.

The high-priority bovine meat-borne hazards *Salmonella* spp. and pathogenic VTEC are not detectable by the visual inspection of slaughtered bovine animals, although rarely they may be associated (e.g. signs of clinical salmonellosis) with certain detected lesions. Visible faecal contamination of carcasses may also indicate potential exposure to the identified high-priority bovine meat-borne hazards. Visual inspection does not mediate cross-contamination of meat with these or other pathogens. Consequently, changes of the currently applied visual examination during *post-mortem* inspection of bovine animals are neither considered nor proposed in this Opinion. Therefore, the proposed generic bovine meat safety assurance framework would not have any effect on detection of other risks targeted and detectable by the current visual examination of carcasses and organs.

As indicated previously (Section 4), the proposed generic bovine meat safety assurance framework, in this document, includes a proposal to omit palpation and incision during *post-mortem* inspection of routinely slaughtered bovine animals that show no abnormalities at *ante-* or *post-mortem* (visual) inspection. The main reason for this is to prevent *Salmonella* spp. and pathogenic VTEC cross-contamination mediated by these manual techniques and, thus, to reduce related bovine meat safety risks. Furthermore, manual handling does not contribute to the control of the identified priority hazards.

Published risk assessments related to pig slaughter (Nesbakken et al., 2003; Pointon et al., 2000) indicated that the release of, and subsequent cross-contamination with, enteric pathogens from lymph nodes can occur as a result of incisions during *post-mortem* inspection of pigs, hence it represents a cross-contamination risk (Pointon et al., 2000). Also, other mandatory inspection procedures, for example, incision of the heart and the examination of other body sites after inspection of the head by the same inspector cause cross-contamination in slaughtered pigs. In a larger study in pig slaughterhouses, a 2.5-fold reduction in combined *Salmonella* spp. and *Y. enterocolitica* contamination prevalence on 800 visually-only inspected finished carcasses (0.25 %) compared with 800 traditionally inspected carcasses (0.63 %) was reported, but the difference was not statistically significant (Hamilton et al., 2002). However, it could be hypothesized that the 2.5-fold reduction found in that very low pathogen-occurrence situation would have been more significant in a higher pathogen-occurrence situation, as the occurrence of these pathogens on pig carcasses can be as high as > 40 % for *Y. enterocolitica* (Van Damme et al., 2010) or *Salmonella* spp. (Small et al., 2006; Blagojevic et al., 2011b).

In respect to ruminants, the presence of *Salmonella* spp. in cattle livers has been shown to rise from 32% at evisceration to 82 % after *post-mortem* inspection (Samuel et al., 1980) demonstrating a rise in cross-contamination as a result of manual inspection procedures. A recent study (Brichta-Harhay et al., 2012) demonstrated that incisions made to inspect lymph nodes in slaughtered cattle led to cross-contamination of surrounding tissues – and consequently resultant minced meat – with *Salmonella*

spp. Furthermore, in an experimental slaughterhouse study at Bristol University (Jankuloski et al., 2009), one set of organs of slaughtered cattle were inoculated with two species of marker bacteria (*E. coli* and *Pseudomonas fluorescens*, distinguishable by selected antibiotic resistance) and subjected to routine *post-mortem* inspection procedure. Subsequently, organs of a number of other non-inoculated cattle were also inspected, in two ways: a) the inspector washed hands (with soap and 45 °C water) and 'sterilised' knife (in 81 °C water) after inspection of the inoculated organs and between each consecutively inspected non-inoculated animals; and b) the inspector neither washed hands nor sterilized the knife between the consecutively inspected animals. After the *post-mortem* inspection, the marker organisms were found on organs of several consecutively inspected (non-inoculated) animals, not only when the between-animal hand washing and knife sterilization were omitted by the inspector but also the organs of some animals when these treatments were conducted. The reasons for the latter include the fact that the hand washing and knife sterilization did not eliminate the marker organisms entirely from the hands and from the knife handles (which stay outside water during the sterilization), respectively, as demonstrated by microbiological examinations.

Practically identical experiments (Jankuloski et al., 2009) conducted with *post-mortem* inspection of sheep also demonstrated that the manual handling during the inspection of organs transferred microbial contamination from inoculated organs (with *E. coli* and *P. fluorescens*) of one sheep to organs of consecutively slaughtered/inspected sheep, and even between-animal hand washing and knife sterilization, as prescribed by the official procedures, did not prevent the cross-contamination.

Overall, while related published experimental data are relatively limited, manual handling used in *post-mortem* inspection procedures (palpation and/or incision of potentially contaminated lymph nodes and organs/muscles) increases the likelihood of microbial cross-contamination of final carcasses and organs. Other related comprehensive considerations also have come to the same conclusion (EFSA, 2004; EFSA Panel on Biological Hazards (BIOHAZ), EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Animal Health and Welfare (AHAW), 2011). Therefore, it is assumed that omitting palpation/incisions during inspection would reduce either the total number of carcasses contaminated with VTEC and *Salmonella* spp., or the total number of the pathogen cells present on the carcasses entering post-slaughterhouse stages of the bovine meat chain, or both. Nevertheless, the extent to which manual manipulation during *post-mortem* inspection contributes to the increase and spread of the high-priority hazards identified (i.e. *Salmonella* spp. and pathogenic VTEC) should be investigated.

Omission of these palpation/incision techniques and conducting visual-only meat inspection is proposed for *post-mortem* inspection of routine slaughter of bovine animals (i.e. on animals that FCI causes no concerns and showing no public health-relevant abnormalities at *ante-* and visual *post-mortem* examination). Based on analysis of knowledge and data on the public health relevance of individual hazards on carcasses (see chapter 2 above on hazard identification and priority ranking), it is considered that the food safety risks of *Salmonella* spp. and pathogenic VTEC cross-contamination during *post-mortem* inspection due to palpation/incision (individually, but especially in combination) exceeds the food safety risks posed by hazards associated with conditions targeted by the palpation/excision within the current meat inspection system. Besides, some of those conditions – those that have no or low public health relevance through meat consumption - can be controlled (i.e. eliminated from the food chain) through a systematic, documented and officially (regulatory) verifiable meat quality assurance system. Importantly, manual manipulation during *post-mortem* inspection does not contribute to the control of the identified priority hazards.

Omission of palpation/incision is not proposed for *post-mortem* inspection of bovine animals processed outside routine slaughter i.e. those suspected when assessing FCI, at *ante-mortem* or *post-mortem* inspection to be diseased or to have a condition that may adversely affect human or animal health ('suspect bovine animals'). These animals should continue to be slaughtered separately from routine slaughter and subjected to detailed *ante-mortem* and *post-mortem* examinations including laboratory testing if necessary. Moreover, if abnormalities of potential meat safety/public health

relevance are detected by routine visual inspection, further examination may be necessary to diagnose them properly, including by application of palpation, incision and laboratory tests as necessary. However, this should be performed in such a way that cross-contamination of carcasses and other organs is prevented (i.e. away from the main slaughterline). Given the particular importance of visual inspection when the examination by palpation/incision is omitted, the conditions for visual inspection e.g. lighting, time and space available need to be such that they ensure its effectiveness.

Any 'non-suspect bovine animals' with abnormalities/conditions that are not of potential meat safety relevance but which are: (a) detected by routine visual meat inspection or (b) passed undetected during routine visual meat inspection but detected during further handling (i.e. carcass and offal trimming) can be removed from the meat chain through a documented, validated, monitored, verified and regulatory audited meat quality assurance system. Such a system could also be designed to include recording of abnormalities/conditions of specific interest and as a point from which relevant information is distributed to other participants of the bovine meat chain and to the FCI.

5.4. Effects of the proposed generic bovine meat safety assurance framework on hazards targeted by the current meat inspection

5.4.1. Effects on *Taenia saginata* cysticercosis

Aiming at detection of *T. saginata* cysticercosis, current bovine meat inspection includes incisions into the internal (pterygoideus) and external (masseter) mastication muscles of all bovine animals older than six weeks and in the heart of all bovine animals followed by visual examination of the cut surfaces.

As indicated earlier, the sensitivity of meat inspection for the detection of *T. saginata* cysticercus is relatively low, for several reasons. First, it is affected by the intensity of the infection of the bovine animal. The sensitivity of detecting light infections (1-10 cysts), which are common, is quite low (27%), and sensitivity increases, up to 78 %, in the case of heavy infections which are less common (EFSA, 2005). Secondly, only between 6.5 % (in mastication muscles) and 15.7 % (in heart) of cysts actually present in infected bovine animals are located within these inspected anatomical sites (Dorny and Praet, 2007). Thirdly, the detection rate is highly dependent on the skills of the meat inspector and the stage of degeneration of the cysticerci. Dead (degenerated) cysticerci are usually better detected, whilst viable cysticerci are seldom detected because they are translucent and blending with the surrounding tissue. Nevertheless, because bovine cysticercosis can include presence of both viable and degenerated cysticerci, the detected cyst's stage is irrelevant for judgement of the fitness of the meat for human consumption. Furthermore, the sensitivity of cysticercosis detection at *post-mortem* inspection also depends, to a certain extent, on the number of incisions made, particularly in the heart, which is a more important predilection site than mastication muscles (Dorny et al., 2000). When additional cuts (more than the mandatory requirement) in the heart were made during meat inspection, approximately a 2.5-fold higher cysticercosis detection rate was achieved (Eichenberger et al., 2011). Due to all these factors, published data suggested that in the EU *post-mortem* inspection-detected prevalence of bovine cysticercosis is roughly 3 to 10-fold lower than actually present (Dorny and Praet, 2007).

During the process of risk (priority) ranking, which placed *T. saginata* into the low-priority category (see Section 2), the decision tree (Figure 1) also included a question to determine whether this low-priority categorisation was due to current meat inspection-based controls. On one hand, because the true prevalence of bovine cysticercosis may be between 3 and 10-fold higher than that detected at meat inspection (Dorny and Praet, 2007), the low-priority categorisation of the hazard could not be attributed predominantly to current meat inspection-based controls (i.e. it detects only a smaller proportion (roughly between 10 and 30 %) of actually presently infected bovine animals). On the other hand, in spite of its low sensitivity, current cysticercosis detection in slaughtered bovine animals helps to some extent in reducing transmission of this parasite to the consumer; particularly as bovine meat is

often eaten undercooked or raw. Although there is little published information to indicate how much would the cessation of incision-based meat inspection for cysticercosis affect public health, a risk assessment model for human infection with *T. saginata* in New Zealand indicated that the mean number of human infections would increase from 0.5-1.1 per year to 0.6-1.3 per year (vanderLogt et al., 1997), which can be translated into roughly a 20 % increase. Overall, it can be presumed that, even if in the risk ranking the data on occurrence of *T. saginata* cysticercus in bovine carcasses were increased by the meat inspection-based detectability factor (i.e. increased by roughly 10-30 %; (Dorny and Praet, 2007)) and data on human infections incidence were increased by the meat inspection-omission factor (roughly 20 %; vanderLogt et al., 1997), the hazard would still be assessed as low-priority based on the criteria applied in the risk ranking activity described in this Opinion. This is in general agreement with a similar conclusion drawn in a recent risk assessment conduced in the UK (AHVLA, 2013).

Based on the above, it can be concluded that the current incision-based *post-mortem* meat inspection of bovine heart and mastication muscles for *T. saginata* cysticercus has a limited impact on protection of meat safety/public health. Hence, if, as proposed, incision were omitted, the related bovine meat safety risk would remain in the low-priority category.

5.4.2. Effects on *Mycobacterium bovis*

During the current *post-mortem* meat inspection process, a number of lymph nodes are routinely palpated/incised with the aim of detecting lesions indicating infections. These include caseous necrosis potentially associated with tuberculosis agents (mycobacteria). Tuberculous-suspected caseous necrosis occurs rarely in slaughtered bovine animals even in countries with known problems of bTB in cattle, e.g. 0.27 % in adult cattle and 0.04 % in calves in the UK (AHVLA, 2013), and occurs mainly in retropharyngeal, pulmonary and intestinal lymph nodes. If mycobacteria are present, the main current concern is zoonotic *M. bovis*.

Issues related to the non-perfect sensitivity of meat inspection for detecting *M. bovis* are discussed in Appendix C of this opinion on Animal Health and Welfare and in Annex A. Furthermore, it is notable that there is no evidence, to date, suggesting that *M. bovis* is a meat-borne hazard for humans in the EU (see Annex A for details), as human infections occur via exposure to other foods (i.e. milk) or the animal environment (direct contact/inhalation). Therefore, it can be concluded that omitting routine incision of lymph nodes during *post-mortem* inspection of bovine animals from routine slaughter would not result in a significant increase in public health risk from *Mycobacterium* spp.; currently the risk is considered as negligible due to the non-meat-borne nature of the agent. On the other hand, it is concluded that routine incision of the lymph nodes could have detrimental effects on bovine carcass meat safety, as it can mediate cross-contamination with *Salmonella* spp. and pathogenic VTEC, which are considered of high-priority for meat inspection at present.

The net result of omitting palpation/incision of lymph nodes should be an overall public health benefit. Nevertheless, in cases where abnormalities on lymph nodes are visually observed, they must be removed as unfit for human consumption and subsequently the lymph nodes and, if necessary, corresponding organ tissues should be subjected to further examinations and testing, including by palpation/incision, but separately from the main slaughterline. It is presumed that this inspection procedure can be ensured through a specified, documented and verifiable process during cutting/boning operations away from the slaughterline – as part of an improved slaughterhouse meat quality assurance system.

5.4.3. Effects on *Mycobacterium avium* subspecies *paratuberculosis*

Mycobacterium avium subspecies *paratuberculosis* (MAP) causes Johne's disease in cattle, with symptoms usually occurring months or years after infection (which usually occurs at a young age) and characterised by weight loss and/or diarrhoea (Davis and Madsen-Bouterse, 2012). Although it was reported that MAP can be present in meat from clinically and subclinically affected cattle (Alonso-

Hearn et al., 2009; Eltholth et al., 2009), the only published study found on the presence of MAP in retail beef failed to find the bacteria in ground beef (Jaravata et al., 2007). Concerning the potential link between Johne's disease and Crohn's disease in humans (Uzoigwe et al., 2007), it should be noted that MAP has also been isolated from patients with other unrelated diseases and from healthy people (Davis and Madsen-Bouterse, 2012). Presently, there is no evidence of meat-borne transmission of MAP to humans. Nevertheless, the zoonotic potential of MAP is still is the subject of current scientific debate and should be further investigated (NACMCF, 2010).

The main *post-mortem* meat inspection findings in cattle include thickening of small intestines and enlargement of associated lymph nodes (Buergelt et al., 1978; Corpa et al., 2000; Greig, 2000), which can be detected by routine palpation and, if/where necessary, incision of gastric and mesenteric lymph nodes. However, as far as the sensitivity of detection of MAP through routine bovine meat inspection is concerned, between 24 % and 53 % of MAP-positive cattle do not have visually identifiable lesions (Buergelt et al., 1978; Brady et al., 2008). Overall, at present, MAP is not considered to be a bovine meat-borne hazard; hence, the meat safety/public health risk from MAP is considered to be low and would remain in the same category (no increase) if palpation of enteric lymph nodes during bovine meat inspection is omitted.

5.4.4. Effects on *Fasciola hepatica*

Fascioliasis (*F. hepatica* infection) is sometimes considered as a zoonotic disease, as it occurs both in animals and humans, but it is not transmissible by ingestion of bovine meat or offal. Human cases occur after ingestion of vegetarion infested with metacercaria of *Fasciola hepatica* (Chand et al., 2009). To detect this liver fluke during current meat inspection of bovine animals, livers are routinely palpated and incised in order to open the bile ducts in bovine animals older than six weeks, whilst only visual inspection is applied in those up to six weeks of age.

The *F. hepatica* detection sensitivity of current bovine meat inspection (by liver incision) is discussed in detail in Appendix C of this Opinion. Values reported in scientific literature considered it to be around 60-70% (Rapsch et al., 2006). This indicates: a) that some *F. hepatica*-containing livers pass through current meat inspection undetected and b) that more *F. hepatica*-containing livers would pass meat inspection if incisions of the liver were omitted. It is difficult to assess more precisely what additional proportion of livers would pass undetected, as some liver fluke infections (e.g. accompanied by cholangitis) are detectable by visual inspection only, particularly in cases of heavier infestations. Published information on the actual ratio of visually detectable versus visually undetectable infections in bovine animals is lacking, and some information based on expert elicitation is presented in Appendix C of this Opinion.

As indicated above, fascioliasis is not transmissible from infected bovine animals to humans via infested livers; hence, the meat safety/public health risk from *F. hepatica* in livers is negligible and would remain in the same category (no increase) if liver incisions are omitted during bovine meat inspection. The fluke-containing parts of the liver are unfit for human consumption on aesthetic/meat quality grounds, and can be removed from the food chain through the meat quality assurance system. The removed parasites should be appropriately inactivated and disposed, in accordance with current EU legislation for animal by-products. Nevertheless, it should be noted that some association of fascioliasis with other microbial infections has also been suggested in older literature (Ogunrinade and Adegoke, 1982). However, these experimental or fortuitous findings are insufficient to assess whether and how significant such other infections may be for public health.

5.4.5. Effects on *Echinococcus granulosus*

Echinococcosis (*E. granulosus*) in slaughtered bovine animals during *post-mortem* inspection is detected by finding of hydatid cysts in parenchymal organs, primarily in liver and lungs (normally not in muscles) by visual inspection or by palpation/incision. The disease is a food-borne zoonosis (Pozio, 2008), but transmission to humans is not via consumption of the infested bovine organs. The parasite

is faecally shed by dogs/canine (definite host) and is transmitted to humans through handling of dogs or contaminated soil/water/food leading to ingestion of the parasite's eggs.

Depending on the stage, hydatid cysts can be quite large and detectable by visual inspection only, while some smaller ones may be visually detectable if located closer to the organ's surface. Small cysts that are located in deeper parts of the organ are detectable by palpation and subsequent incisions into the tissue made in palpation-suspect cases. Meat inspection sensitivity related issues for detecting *E. granulosus* hydatidic cysts are presented Appendix C of this Opinion.

As *E. granulosus* is a non-meat-borne hazard, the meat safety risk is negligible in the current inspection system, and would remain in the same category if related palpations/incisions were omitted during *post-mortem* meat inspection of bovine animals. The hydatid cyst-containing tissues are unfit for human consumption on aesthetic/meat quality grounds, and can be removed from the food chain through the meat quality assurance system. The removed cysts should be appropriately inactivated and disposed, in accordance with current animal by-products EU legislation. This represents an important echinococcosis control measure aimed at breaking the parasite's life cycle through prevention of dog infections through by-products (the other control measure being controls of infected dogs).

5.4.6. Effects on other abnormalities/conditions that are not specifically targeted by specified procedures

A number of abnormalities/conditions can be detected during *post-mortem* meat inspection of bovine animals. Although they are not targeted by a specified inspection procedure, they are found 'accidentally' during routine visual/palpation/incision-based examinations. They include abscesses in various locations, septicaemia, hepatitis, and non-zoonotic parasites in lungs. Abscesses are caused by non-zoonotic microorganisms, by microorganisms that are zoonotic but not transmissible to humans *via* bovine meat consumption (*Streptococcus* spp.), or by those that represent a low meat safety risk (*S. aureus*) but cause food-borne harm only if present in high numbers. In many cases abscesses are detectable visually. Bovine animals with acute septicaemia would show clinical symptoms at *post-mortem* inspection. Hepatitis can be caused by several agents and is often secondary infection or metabolic condition; it is presumed that it is usually visually detectable (liver enlargement, change of colour). Overall, it is considered that omitting mandatory palpations/incisions during *post-mortem* inspection would not increase bovine meat safety risks from all these conditions, with the only exception of a slightly increased risk of *S. aureus*, but which is a hazard excluded from the priority ranking as it is related to growth or introduction on carcass or meat at post-chill steps (see Section 2.2.3.). Furthermore, as indicated above, detection of abnormalities that are not a meat safety risk (e.g. non-zoonotic parasites) and removal of affected parts as unfit for human consumption can be ensured through a verified meat quality assurance system.

5.4.7. Effects on emerging and/or re-emerging risks

The outlined and proposed generic bovine meat safety assurance framework targets the hazards that are considered the most relevant at the time of preparation of this Opinion. One of the main intentions of the proposed approach is to have a flexible and risk-based framework, adaptable to variable and changeable situations occurring in practice with time.

In accordance with this goal, if the risks from the existing hazards targeted by the proposed framework significantly decrease over time, it is expected that the main focus of the system would be redirected towards other hazards that might have become of relatively higher priority. For example, new hazard(s) posing a significant bovine meat safety risk might emerge and/or the risks from existing hazards that presently are not high-priority (e.g. *Campylobacter* spp., *T. saginata* cysticercus) might increase over time or in some regions. Therefore, it is important that the proposed framework be used in association with a robust zoonoses monitoring/surveillance system and accompanied by alert mechanisms for emerging risks, which would enable timely notification of significant changes in bovine meat safety risks.

Reliable epidemiological data about zoonotic agents in slaughtered bovine animals and incidence of human disease caused by these agents are needed for each country/region, as such information is a crucial to any change from a strictly uniform bovine meat inspection system to a dynamic FCI- and risk-based system. If/when the situation changes significantly, it would be advisable for the proposed framework to be re-evaluated in terms of its ability to handle the emerged/re-emerged risks following necessary adaptations. It is expected however that the main spirit and principles of the proposed framework (FCI incorporating risk categorisation of batches of bovine animals and slaughterhouse processes, verifiable HACCP-based risk reduction strategies, as well as hazard-related targets for bovine carcasses) will continue to be the foundation of future adaptations of this framework.

5.5. Conclusions and recommendations on recommended adaptations of inspection methods for hazards currently addressed and the impact of the proposed changes on these hazards

FCI can be improved by including information on participation in quality assurance schemes and by improved feedback to the primary producer, as this would likely result in the production of healthier animals.

Ante-mortem inspection assesses the general health status of animals and helps in the detection of animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current visual inspection methods do not increase the microbiological risk to public health, no adaptations for the existing visual *ante-mortem* inspection are required or recommended.

Visual *post-mortem* inspection of bovine carcasses can detect faecal contamination that may indicate potential exposure to the identified high-priority hazards. However, palpation/incision, as used in current *post-mortem* inspection, should be omitted in the case of bovine animals subjected to routine slaughter, because these procedures do not add to the identification and control of the high-priority bovine meat-borne hazards and may increase their spreading and cross-contamination.

Manual techniques of examination should be limited to suspect bovine animals and should be performed, where appropriate, separately from the slaughterline operation. Abnormalities on aesthetic/meat quality grounds can be eliminated through an adequate meat quality assurance system, which may also detect abnormalities associated with non-meat-borne and low-priority hazards, as well as related data recording and distribution.

Further research is needed on the extent to which manual manipulation during *post-mortem* inspection contributes to increasing spreading and cross-contamination of the high-priority hazards identified (i.e. *Salmonella* spp. and pathogenic VTEC) and possible methods to reduce this risk.

The effect of the omission of palpation and incision on the meat safety risk posed by low-priority meat-borne hazard such as *Taenia saginata* cysticercosis and on the public health risk posed by non meat-borne hazards such as *Echinococcus granulosus* should be periodically re-visited in the future, particularly in those regions where those hazards are endemic.

An assessment of the historical data over a time period could also be used for optimising the sampling and testing frequency for the main hazards in order to focus control efforts where the risk is highest.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

These conclusions and recommendations refer only to biological, meat-borne public health hazards in the context of bovine meat inspection.

It was determined that within a true risk-based meat inspection concept, it is not necessary to design and apply a separate meat inspection system for individual bovine species or farming systems or animal age categories. Rather, a universal meat inspection framework can be designed and applied that would allow risk categorisation of animals based on individual farm-related food chain information (FCI), which also includes farming system and animal age category components.

Term of Reference 1: ***Identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e .g. breeding compared to fattening animals).***

- A decision tree was developed and used for priority ranking bovine animal meat-borne biological hazards. Hazards that are introduced and/or for which the risk for public health requires bacterial growth during processing steps after carcass chilling (*Listeria monocytogenes*, and toxins of *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus aureus*) were excluded at the first stage of the ranking and not considered further.

- Based on the limited data available and expert opinion, biological hazards categorised as low-priority for bovine meat inspection were *Bacillus anthracis*, *Campylobacter* spp. (thermophilic), *Sarcocystis hominis* and *Taenia saginata*. These hazards were not considered further because it was determined that their low-priority ranking was not due to current controls (i.e. any hazard-specific control measures implemented at farm and/or slaughter level before chilling of the carcasses, including current meat inspection procedures). However, the effect of carcass chilling on reduced survival of *Campylobacter* spp. (thermophilic) on carcasses of bovine animals as a non-hazard-specific control measure has to be taken into account.

- The bovine meat-bone biological hazards categorised as of high-priority for meat inspection were *Salmonella* spp. and pathogenic verotoxigenic *Escherichia coli* (pathogenic VTEC).

- *Toxoplasma gondii* and extended spectrum and/or AmpC β-lactamases (ESBL/AmpC) gene carrying *E. coli* were carachterised as of 'undetermined' priority for bovine meat inspection because available data were insufficient for conclusive ranking.

Term of Reference 2*: Assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at post-mortem or Post-mortem inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.*

The assessment of the strengths and weaknesses of the current meat inspection was primarily focused on its contribution to the control of the identified high-priority bovine meat-borne biological hazards.

- Strengths of the current meat inspection methodology for the high-priority biological hazards are as follows:

  - In principle, adequate collection and proper utilisation of Food Chain Information (FCI) can be useful and beneficial in *ante-* and/or *post-mortem* bovine meat inspection. FCI, used as part of *ante-mortem* inspection, provides information related to veterinary treatments and disease history during animal rearing and helps focus *ante-mortem* and/or *post-mortem* meat inspection on animal and public health concerns.

  - *Ante-mortem* and *post-mortem* inspection of bovine animals and carcasses enable detection of visible abnormalities, providing important benefits in monitoring animal health and welfare.

  - *Ante-mortem* inspection of bovine animals enables animal identification for traceability, and can be used to verify FCI given by the farmer and to provide feedback to producers on problems detected, but usually for issues not related to public health. *Ante-mortem* visual examination detects bovine animals with diarrhoea as well as visible faecal contamination that may be associated with increased risk of microbial cross-contamination during slaughter.

  - *Post-mortem* inspection detects visual faecal contamination on dressed bovine carcasses that may indicate potential exposure to the identified high-priority bovine meat-borne hazards.

- Weaknesses of the current meat inspection methodology for high-priority biological hazards are as follows:

  - Currently, FCI collection is not harmonised, is used only to a limited extent, and is not adequate to allow classification of bovine farms/herds in relation to potential presence of the identified high-priority bovine meat-borne biological hazards *Salmonella* spp. and pathogenic VTEC.

  - Current *ante-mortem* and *post-mortem* macroscopic inspection are not able to detect any of the identified high-priority bovine meat-borne biological hazards.

  - Judgement of the fitness of bovine meat for human consumption by current *post-mortem* inspection does not differentiate food safety aspects from meat quality aspects, prevention of animal diseases, and occupational hazards.

  - Manual handling of meat, including use of palpation/incision techniques, during *post-mortem* inspection does not contribute to the detection of the identified high-priority bovine meat-borne hazards; in fact, it may increase and spread these hazards by cross-contamination.

Term of Reference 3*: If new hazards currently not covered by the meat inspection system (e.g. Salmonella, Campylobacter) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.*

- Since none of the bovine meat-borne biological hazards categorised as of high-priority can be detected by traditional macroscopic meat inspection, other approaches are necessary to control these hazards. This can be best achieved using FCI and risk-based controls along the farm to chilled bovine carcass continuum.

- An integrated bovine meat safety assurance system has been outlined and includes the need for clear and measurable high-priority meat-borne hazard-based EU targets (hazard prevalence and/or concentration) to be achieved by Food Business Operators (FBOs) in/on bovine carcasses and, when appropriate, in bovine farms/herds.

- Risk-based targets derived from harmonised monitoring are not yet available for the bovine meat-borne biological hazards categorised as of high-priority for meat inspection (i.e. *Salmonella* spp. and pathogenic VTEC).

- An important element of an integrated bovine meat safety assurance system should be risk categorisation of farms/herds of bovine animals based on farm descriptors and historical data as well as herd-specific information, including monitoring of Harmonised Epidemiological Indicators (HEI) as described in the related Scientific Report of EFSA[14].

- Significant differences exist among bovine farms/herds in farming practices, risk factors and controls used in respect to *Salmonella* spp. and pathogenic VTEC, and thus potentially in the corresponding status of bovine animal batches sent to slaughter. This indicates that it should be possible to risk categorise bovine animal batches sent to slaughter for *Salmonella* spp. and pathogenic VTEC through use of FCI, based on farm/herd historical data, and information gathered through application of appropriate HEI.

- Risk categorisation of slaughterhouses should be based on trends of data derived from Process Hygiene Assessments (PHA) and from Hazard Analysis Critical Control Point (HACCP) programmes. Improvement of slaughter hygiene through technological and managerial interventions should be sought in slaughterhouses with repeatedly unsatisfactory performance.

- High-risk animal batches or herds should be subjected to additional slaughter hygiene control measures and possibly complemented with decontamination treatments, or might be directed to slaughterhouses having demonstrated an enhanced ability to control carcass contamination. Where necessary, meat derived from carcasses of high risk animals may be used only for heat processed or cooked products. Animal batches of unknown risk category for a given hazard or mixed batches that include animals of unknown or high risk category for a given hazard should be handled as of high risk.

Term of Reference 4*: Recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria (see annex 2). When appropriate, food chain information should be taken into account.*

- FCI can be improved by including information on participation in quality assurance schemes and by improved feedback to the primary producer, as this would likely result in the production of healthier animals.

- *Ante-mortem* inspection assesses the general health status of animals and helps in the detection of animals heavily contaminated with faeces on arrival at the slaughterhouse. Taking these factors into consideration, and given that current visual inspection methods do not increase the microbiological risk to public health, no adaptations for the existing visual *ante-mortem* inspection are required or recommended.

[14] European Food Safety Authority, 2013. Technical specifications on harmonised epidemiological indicators for biological hazards to be covered by meat inspection of bovine animals. EFSA Journal 2013;11(6):3276, 78 pp. doi:10.2903/j.efsa.2013.3276

- Visual *post-mortem* inspection of bovine carcasses can detect faecal contamination that may indicate potential exposure to the identified high-priority hazards. However, palpation/incision, as used in current *post-mortem* inspection, should be omitted in the case of bovine animals subjected to routine slaughter, because these procedures do not add to the identification and control of the high-priority bovine meat-borne hazards and may increase their spreading and cross-contamination.
- Manual techniques of examination should be limited to suspect bovine animals and should be performed, where appropriate, separately from the slaughterline operation. Abnormalities on aesthetic/meat quality grounds can be eliminated through an adequate meat quality assurance system, which may also detect abnormalities associated with non-meat-borne and low-priority hazards, as well as related data recording and distribution.

RECOMMENDATIONS

- Hazard identification and associated priority or risk ranking should be revisited regularly as new hazards might emerge and/or hazards that presently are of undetermined or low-priority might become more relevant in the future, in some regions, or as more data become available.
- To provide a better evidence base for future rankings the following should be undertaken: (i) systematic collection of data for source attribution of the identified bovine meat-borne hazards, and (ii) collection of data to identify and rank emerging bovine meat-borne hazards.
- All parties involved in the proposed integrated meat safety assurance system should be trained in the skills required.
- Research is needed on optimal ways of using the collected FCI data for risk categorisation of bovine farms/herds, as well as approaches for assessing public health benefits (e.g. by means of source attribution methods).
- For risk categorisation of slaughterhouses, baseline data collection and development of approaches for slaughterhouse PHA through use of indicator organisms are needed.
- In regions where *Salmonella* spp. is not controlled at farm level, preventive measures should be implemented in order to avoid its introduction in negative holdings or regions.
- Further research is needed on the extent to which manual manipulation during *post-mortem* inspection contributes to increasing spreading and cross-contamination of the high-priority hazards identified (i.e. *Salmonella* spp. and pathogenic VTEC) and possible methods to reduce this risk.
- The effect of the omission of palpation and incision on the meat safety risk posed by low-priority meat-borne hazard such as *Taenia saginata* cysticercosis and on the public health risk posed by non meat-borne hazards such as *Echinococcus granulosus* should be periodically re-visited in the future, particularly in those regions where those hazards are endemic.

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ANNEXES

Annex A. Evidence for excluding some biological hazards from further consideration

1. *Giardia duodenalis* and *Cryptosporidium parvum*

Cryptosporidium parvum and *Giardia duodenalis* are protozoan parasites that cause intestinal infections (giardiasis and cryptosporidiosis) in man and animals. Although both parasites have a distinct taxonomic position, they are often considered together because of their similar epidemiology. Their life cycle is completed within a single host, with transmission by the (oo-)cysts, which are produced in large numbers and are infectious when excreted; they are transmitted by the faecal–oral route, either through direct contact or by contamination of food and water supplies. The parasites have a low infective dose (Okhuysen et al., 1999; Rendtorff, 1954). In addition, the (oo-)cysts are very resistant to environmental and water treatment stresses, which assists their dissemination. These parasites are cosmopolitan pathogens with a very wide host range, including domestic and wild animal species, and humans. Molecular characterisation has revealed significant genetic variation and uncertainty about host-specificity and zoonotic potential of isolates. There is concern that cattle could represent a reservoir of some *G. duodenalis* and *C. parvum* genotypes with the potential to cause disease in humans (Thompson et al., 2008). Although the zoonotic potential of some *C. parvum* genotypes has been established, the zoonotic potential of *G. duodenalis* genotypes is less clear. Extensive faecal excretion of these parasites is observed mainly in pre-weaned calves.

C. parvum causes acute gastrointestinal disorders in humans that are usually mild and self-limiting in immunocompetent hosts but that can be severe and even life-threatening in immunocompromised persons. *G. duodenalis* can cause asymptomatic colonization of the small intestine or acute or chronic diarrheal illness. It is a common cause of chronic diarrhoea and growth retardation (Feng and Xiao, 2011).

At present, no data on bovine-meat attribution available to date for *C. parvum* and *G. duodenalis* are available. The USA Department of Agriculture (USDA) states on its website[15]: "*Giardiasis is frequently associated with drinking contaminated water, but some people might get infected by consuming uncooked meat also contaminated with G. duodenalis cysts (the infective stage of the organism)*."

In addition, the following should be considered:

- Bovine borne infection by *G. duodenalis* and *C. parvum* has not been demonstrated to date;
- The most common infection route for *C. parvum* and *G. duodenalis* is faeco-oral (human to human);
- Water-borne infections occur with both parasites, and parasite-contaminated water can contaminate food. It has ben suggested that strains of animal origin can be transmitted via the water-borne route. Nevertheless, for *G. duodenalis* this is less clear;
- Although the zoonotic potential of some *C. parvum* genotypes has been established, the zoonotic potential of *G. duodenalis* genotypes is less clear;
- Young animals (1-4 months old for *G. duodenalis*, a few weeks old for *C. parvum*) shed large amounts of *G. duodenalis* cysts and *C. parvum* oocysts; and

[15] See details at: http://www.fsis.usda.gov/FACTSheets/Parasites_and_Food-borne_Illness/index.asp

- For *Cryptosporidum* spp. there seems to be a succession of different species with age of the cattle (the zoonotic *C. parvum* being replaced by other non-zoonotic species as the animals grow older).

As a consequence, at present, there is no evidence to suggest that either *G. duodenalis* or *C. parvum* are bovine meat-borne hazards for humans.

2. *Mycobacterium bovis*

M. bovis is a zoonotic agent that can cause a condition very similar to human tuberculosis. The human infection occurs typically through contaminated aerosol inhalation or direct contact with animal mucous membranes (Grange and Yates, 1994; Ashford et al., 2001). The introduction of milk pasteurisation and tuberculin screening of cattle herds has largely eliminated the public health risk from *M. bovis* which in the past was a common cause of milk-borne tuberculosis infections in humans (Grange and Collins, 1997; de la Rua-Domenech, 2006; HPA, 2010).

As indicated above, to determine whether *M. bovis* in cattle should be included in the hazard prioritization list for bovine meat inspection, scientific information to be considered is whether: a) the organism is presently found in bovine meat in the EU; and b) there is a risk of its transmission to humans via the meat-borne route.

To date, only a limited number of published studies have reported on the presence of *M. bovis* in bovine meat and organs. Three recent studies reported on isolation of *M. bovis* from carcass lymph nodes (i.e. both visceral and non-visceral related lymphoid structures) and in offal but not in muscle samples (ACMSF, 2003; Beswick, 2004; Van der Merwe and Michel, 2010). Eight older studies reported on the isolation of *M. bovis*, to different degrees, from bovine muscles (Cohrs and Obiger, 1954; Drieux, 1957; Francis, 1958; Gallo and Guercio, 1956a, 1956b, 1957; Hubert et al., 1975; Meyn and Schliesser, 1954; Tison et al., 1966); however, the large majority of them originated from tuberculin-positive animals or animals showing multiple or generalised tuberculosis lesions at *post-mortem* inspection.

In relation to meat-borne transmission potential, only two very old studies (M'Fadyen, 1890; Francis, 1958) reported transmission of tuberculosis to fur animals or experimental laboratory animals following feeding with meat or meat juice from tuberculous bovine animals. Presently, there is a consensus in the published literature that there is no evidence of transmission of *M. bovis* to humans through consumption of bovine meat.

However, the reported lack of evidence of the potential for meat-borne transmission of *M. bovis* has to be considered in light of difficulties in designing experimental studies to further investigate whether and to what extent a meat-borne *M. bovis* transmission to humans is possible under the current epidemiological situation in Europe. Hence, some published studies have considered that meat-borne transmission of *M. bovis* is possible, and thus reflected on the level of public health risk.

M. bovis is recorded as accounting for 1–3% of clinical cases of human tuberculosis reported each year in the EU (EFSA and ECDC, 2011, 2012b, 2013), although it is not known if infected-but-asymptomatic individuals exist and, if so, how many. Recent analysis of published information and data reporting on *M. bovis* tuberculosis in the United Kingdom (Hill et al., 2013), which is one of the countries with the highest prevalence of bovine tuberculosis (bTB) in cattle in the EU, indicated that out of 9 153 reported human cases of tuberculosis in 2009, less than 50 (i.e. <0.5% of all tuberculosis cases) were due to infection with *M. bovis*. The majority of those *M. bovis* cases were in people over 65 years who had consumed unpasteurised milk in the past, or those of any age who picked up the infection abroad (HPA, 2010). Recent epidemiological studies, carried out in the United Kingdom did not find an increase in the number of human cases despite an increase in cattle cases in the same country (Jalava et al., 2007; Stone et al., 2011). Furthermore, exposure to *M. bovis* via bovine meat

inspected and deemed fit for human consumption can not be excluded. This is because the sensitivity of meat inspection for detecting cases is not 100 % (as discussed with detail in the Animal Health and Welfare related Appendix of this Opinion), thus allowing for *M. bovis* positive carcasses entering the food chain. Thus, for example, despite the significant burden within the cattle population (>1% of herds are infected), the UK Health Protection Agency classifies the current risk to human health from food-borne *M. bovis* as negligible (HPA, 2010).

Other reports, theoretically addressing – should it be possible - the meat-borne *M. bovis* risk, qualify the risk as 'very low' or 'negligible', and linked to consumption of uncooked or undercooked bovine meat (ACMSF, 2003; de la Rua-Domenech, 2006; Francis et al., 1973; FSAI, 2008; Moda et al., 1996; NZFSA, 2006; O'Reilly and Daborn, 1995; Pritchard, 1988; Roberts, 1986; Thoen et al., 2006). Quantitative estimates are not available in the literature. Therefore, current control measures for bTB in slaughterhouses in the EU (i.e. mandatory cutting of lymph nodes and partial or full condemnation of carcasses at meat inspection) are not actually based on public health risk; rather, they are based on the intention to and the belief that they: a) prevent (presently not documented) potential meat-borne transmission of the disease; and b) provide information for the effectiveness of applied animal health controls and are an important element of national bTB eradication programmes, as described in the animal-health related Annex of this Opinion.

Summarising, it can be concluded that, currently, there is no evidence suggesting that *M. bovis* is a meat-borne hazard for humans in the EU.

3. *Yersinita enterocolitica* and *Yersinia pseudotuberculosis*

Case-control studies have not identified consumption of bovine meat as a source of human yersiniosis.

Meat-borne transmission of *Y. enterocolitica* has been associated through consumption of pork (Fredriksson-Ahomaa, 2007; Sabina et al., 2011; NSCFS, 2012). *Y. enterocolitica* has been isolated from cattle in the UK (McNally et al., 2004) and positive results in serological control programs for brucellosis in cattle have in some cases proved to be cross-reactions with *Y. enterocolitica* 2/O:9 antigens(Wauters, 1981; Weynants et al., 1996). The microorganism has been isolated from beef (Fredriksson-Ahomaa, 2007; Sabina et al., 2011). However, up to now, the food-borne link between bovine animals and humans yersiniosis has been reported to be milk-borne based on yersiniosis outbreaks (Fredriksson-Ahomaa, 2007; Sabina et al., 2011; Nesbakken, 2012).

Transmission of *Y. pseudotuberculosis* via milk to humans has been reported, but there is no evidence of transmission via consumption of bovine meat (Fredriksson-Ahomaa, 2007)

In conclusion, it is considered that currently there is no evidence of the bovine meat-borne transmission of human yersiniosis.

Annex B. Brief summary of main on-farm practices for controlling *Salmonella* and pathogenic VTEC on farms of bovine animals

1. Prevention of recycling of pathogens in the environment

Inappropriate land management, e.g. use of untreated animal faeces-based farm and/or slaughterhouse wastes (manure, slurry) as fertilisers can lead to infections and/or re-infections of animals with *Salmonella* spp. and pathogenic VTEC previously faecally shed by bovine animals. The main transmission routes include grazing on treated land, animal feed harvested from such land, and contaminated water supplies (Hutchison et al., 2000; FSA, 2002; Pepperell et al., 2003; Heines and Staley, 2004; Hutchison et al., 2004). The main control practices to prevent re-cycling of *Salmonella* and pathogenic VTEC include:

- Preventing animals from accessing slurry pits / dung heaps.
- Sufficiently lengthy storage (e.g. one to three months) of slurry/manure prior to spreading so that bactericidal temperatures are reached within the wastes.
- Maximising the time interval between spreading and harvesting of the next crop intended for feed.
- Leaving pastures without grazing for at least one month or until all visible signs of animal waste have disappeared.

2. Prevention of introduction and/or spreading of pathogens within the farm

The purchase of bovine animals that are *Salmonella* spp. and/or pathogenic VTEC shedders is an important source of introduction of these pathogens on farms. The main risk-reduction practices include purchasing animals only from controlled sources of known status for these pathogens, and implementation of the so-called 'all in-all out' farming system with effective sanitation between animal lots. As pathogens can be introduced into the farm/herd from infected wildlife and/or vermin, infected or contaminated farm staff/visitors, and contaminated farm equipment, effective preventative biosecurity measures are needed to minimise exposure of the animal population to these vectors.

Once the pathogens are introduced into a bovine animal farm, they are spread by close proximity of animals (especially associated with group housing/intensive indoor farming) mediating direct physical contact among animals and between animals and contaminated surfaces, and common use of feeders/drinkers. The prevention/reduction of within-farm spread of *Salmonella* spp. and pathogenic VTEC is greatly dependent on the level of hygiene in the animal production environment. *Salmonella* spp. and pathogenic VTEC can survive days or months in/on substrates such as faeces, soil, water and building materials (Hutchison et al., 2000). They generally survive better under dirty/humid/cold conditions than under clean/dry/warm environmental conditions (Small et al., 2003); the survival rates are also strain-dependent (Avery and Buncic, 2003). Hence, use of effective cleaning/sanitation programmes is particularly important.

3. Prevention of ingestion of pathogens by animals

Obtaining feed from controlled sources and storing feed in vermin-proof feed storage facilities until use, are important elements of the on-farm meat safety system. To reduce ingestion of *Salmonella* spp. and/or pathogenic VTEC by animals in indoor-farms, feed can be subjected to antimicrobial treatments such as fermentation (i.e. silage) or acidification; but this is not possible in outdoor (grazing) farming situations. A review of pre-harvest controls (LeJeune and Wetzel, 2007) concluded that eliminating VTEC O157 from drinking water for cattle may be a meritorious goal, but that practical, economical, and effective water treatments have not been demonstrated to significantly affect VTEC O157 epidemiology.

4. Suppression of pathogens within animal gastro-intestinal tracts

A number of experimental studies have indicated that on-farm animal shedding of *Salmonella* spp. and pathogenic VTEC may be reduced by use of selected diets; for example, the risk of VTEC O157 shedding has been reported to be increases by feeding of hay, grain or molasses and a reduced risk with barley or grass silage (Busato et al., 1999; Rugbjerg et al., 2003). However, diet-related findings are still being debated, and direct comparison between studies of the effects of given diets on pathogen shedding in bovine animals is very difficult because a range of animal- and/or farm-related factors varying between studies, interfere with the results (Jacob et al., 2009).

Furthermore, to suppress *Salmonella* spp./pathogenic VTEC within the bovine intestinal tracts, various approaches have been investigated or proposed, including feeding:

- Viable microorganisms exhibiting antagonism toward pathogens, as they either modify the gut environment or produce certain antimicrobial compounds – a so-called 'probiotic' strategy (Fuller, 1989). Numerous probiotics have been identified and tested for efficacy in controlling VTEC O157 in cattle (Berry and Wells, 2010) with varying results depending on probiotic microorganisms used.

- Selected nutrients (sugars or other organic compounds) indigestible by bovine animals but utilised by microorganisms, so to enhance competitiveness of the normal gut microbiota – the so-called 'prebiotic' strategy (Walker and Duffy, 1998; Steer et al., 2000).

- Selected, non-pathogenic bacterial strains that reduce attachment of the pathogens to the gut mucosa – the so-called 'competitive exclusion' strategy (Nurmi et al., 1992); this approach has been used primarily in monogastric animals and rarely in ruminants.

- Bacteriophages preying on bacterial pathogens e.g. VTEC O157 (Kudva et al., 1999).

5. Enhancement of animal host response

Vaccination of cattle against *Salmonella* strains causing disease has been successfully used (House et al., 2001). In large-scale clinical trials of Econiche™ the vaccinated cattle were 92 % less likely than non-vaccinated cattle to be colonised with VTEC O157, while in a second study the vaccine's efficacy was reported to be 63 % (Smith et al., 2009a, 2009b).

In addition, stress in bovine animals may reduce their resistance to colonisation with pathogens, e.g. *Salmonella* spp., resulting in increased shedding. Whilst some stressors are 'inevitable' (e.g. parturition, weaning), other stressors (e.g. poor animal husbandry practices, sudden changes in diet and rough handling) can be successfully prevented or reduced. On the other hand, in a study by Brown-Brandl et al. (2009), no evidence was found to suggest a relationship between either handling or heat stress with generic *E. coli* concentrations or VTEC O157 concentrations and prevalence in cattle faeces.

6. Prevention and/or reduction of pathogen spreading during transport

Because cross-contamination occurs between bovine animals during the farm-to-slaughterhouse phase (Collis et al., 2004), spread of pathogens such a *Salmonella* spp. and pathogenic VTEC can be reduced by minimising the duration of this phase, as well as through sanitation of vehicles and pens – which has to be effective as *Salmonella* spp. and pathogenic VTEC can persist on surfaces even after routine sanitation (Small et al., 2002; Tutenel et al., 2003).

Withdrawal of feed just before transport of bovine animals, as a means reducing the excretion of faeces and related microbial contamination, has been studied – but this practice was found in fact to

increase shedding of VTEC O157 and *Salmonella* spp. by cattle (Frost et al., 1988; Delazari et al., 1998; Cray et al., 1998).

7. Other on-farm aspects related to *Salmonella* spp. and pathogenic VTEC

These include:

- **Subspecies characteristics of pathogens**. The most common *Salmonella* serovars infecting cattle include *S.* Dublin, *S.* Typhimurium, *S.* Newport, and *S.* Montevideo, and cattle can be diseased or become asymptotic carriers for variable periods. Clinical salmonellosis is more commonly associated with some serovars (e.g. *S.* Dublin is well adapted to cattle than with others (Ekperigin and Nagaraja, 1998)).

- **Age category**. This factor may have varying effects, depending on the pathogen. For example, young calves are more susceptible to *Salmonella* spp. than other age groups (Hinton et al., 1983). However, it seems that VTEC carriage and shedding may be lower in very young calves, <2 months (Rhoades et al., 2009). Shedding increases in calves 2-18 months of age (Ellis-Iversen et al., 2007); but this ma be partly due to poor bedding hygiene and larger groups of animals housed together more often taking place post-weaning. Nevertheless, weaned calves have been reported to excrete VTEC O157 more frequently and in greater numbers than adult animals (Ellis-Iversen et al., 2008).

- **Individual animal variability in shedding pattern**. Some bovine animals excrete more VTEC O157 than others and are called super-shedders (Chase-Topping et al., 2008; Naylor et al., 2003). Super-shedding has been observed to be associated with colonisation at the terminal rectum and might also occur more often with certain pathogen phage types. Although the nature and the determinants of super-shedding currently are understood only to a limited extent, control measures targeting super-shedders may prove to be particularly effective. Possible strategies for the on-farm control of VTEC O157 based on the detection and removal of super-shedding cattle, or testing before movement of individual animals (Chase-Topping et al., 2008; Naylor et al., 2003) have been suggested. However, these are presently theoretical approaches that have yet to be proven or implemented in a commercial environment (AHVLA, 2013).

- **Seasonal variability of shedding**. The prevalence of VTEC in animals as well as the shedding and faecal concentration of VTEC have been reported to be increased in the summer and early autumn (Elder et al., 2000; Sargeant et al., 2003). Furthermore, clinical bovine salmonellosis also may be higher in the summer and autumn, near the end of the grazing season (Williams, 1975).

8. Differentiation and control of farms in respect to *Salmonella* spp. and pathogenic VTEC status

The emergence of *Salmonella* spp. is often related to changes that have occurred in livestock farming, as farm sizes have increased and animal husbandry methods have also become more intensive. However, monitoring and control programmes established during the early 1990s in Finland, Norway and Sweden have indicated that less than 0.1% of the cattle in these countries are carriers of *Salmonella* spp., suggesting that it is possible to control this agent by categorisation at herd level (NCM, 2006). Surveillance and control of *Salmonella* spp. has been a major focus for the competent authorities and the meat industry in Finland, Norway and Sweden, and culturing methods have been the basis for the survey programmes established (Maijala et al., 2005; NCM, 2006). Based on results of mesenteric lymph nodes sampled and tested at the slaughterhouse, positive herds are traced. Farms and herds infected with *Salmonella* spp. are subject to specific restrictions, including separate transportation and slaughtering, for instance at the end of the workday. Carcasses from positive herds are swabbed and tested for *Salmonella* spp., and positive carcasses are heat-treated or condemned.

From a more global perspective, preventive measures should be implemented in order to avoid introduction of *Salmonella* spp. in holdings or regions that were previously *Salmonella* spp. negative from regions where *Salmonella* spp. is not controlled at farm level. This can be achieved, for example, first establishing (by means of surveillance) large population units (e.g. regions) where the zoonotic agent is not found and then ensuring that the agent is not introduced into these areas by purchasing live animals only from areas where it was not detected.

Annex C. Review of slaughterhouse practices for controlling *Salmonella* spp. and pathogenic VTEC

1. Control options related to slaughterhouse operation-mediated cross-contamination

Control options in the context of the slaughterhouse operation-mediated cross-contamination can be classified in those linked to: (i) the visual cleanliness of bovine animals; (ii) the hygienic dressing operations during the slaughter operation; (iii) the use of carcass decontamination treatments; (iv) carcass chilling; and (v) general management of microbial risks during the slaughterhouse operation. Further details are presented below.

1.1. Visual cleanliness of bovine animals

Pathogenic VTEC and *Salmonella* spp. are shed in the faeces and often contaminate the hide. Bovine animals should be visually clean before slaughter in order to reduce general slaughterhouse contamination and both direct and indirect cross-contamination of carcasses (Davies et al., 2000). Regulation (EC) No, 853/2004 requires that bovine animals presented for slaughter should be clean, a concept supported by CAC (2005). Consequently, a visual scoring system for extent of external animal faecal contamination is used in many countries in Europe and visual inspection of the hide for faecal contamination is part of the *ante-mortem* inspection activities. A clean cattle policy at slaughter is in operation in countries like Ireland, the United Kingdom and France. According to this, bovine animals are subject to visual inspection and assigned a cleanliness score, even though there are differences in the visual scoring systems used among countries. Usually, bovine animals arriving at the slaughterhouse are categorised based on the degree and anatomical location of faecal material, dirt and other contaminants such as straw bedding. In Ireland, for example, bovine animals presented for slaughter are divided into five categories by the official veterinarian during *ante-mortem* inspection (Anon, 1997). In the United Kingdom a similar categorisation is used with excessively dirty bovine animals being rejected (FSA, 2007). Special hide cleanliness requirements are also in place in Finland, Sweden and Norway (Hauge et al., 2012). Excessively dirty animals are either rejected for slaughter, or slaughtered separately at the end of the day (logistic slaughter) with reduced line speed. In some countries bovine animals may also have the hides clipped to remove dirt and faeces, even though the effectiveness of this procedure in terns of achieving a better microbial status of the resultant carcass is not clear from existing scientific literature (Baird et al., 2006; Small et al., 2005). Currently, assessment of visual cleanliness of bovine animals is doubled i.e. it is executed by both the FBO and the official authority. The former is done as part of GHP programmes, or even as part of related Critical Control Points (CCPs) monitoring procedures within HACCP plans in some slaughterhouses, and the latter as part of *ante-mortem* inspection.

Overall, it has been widely assumed that the 'visually dirtier hides' generally lead to 'microbiologically dirtier carcasses' (Kiermeier et al., 2006; Ridell and Korkeala, 1993; Tergney and Bolton, 2006) in terms of both indicator organisms (Serraino et al., 2012) and pathogens such as VTEC O157 (Blagojevic et al., 2012b). Therefore, hide cleanliness is considered important in bovine meat hygiene, and operating a clean livestock policy is especially relevant for the control of pathogenic VTEC and *Salmonella* spp.

However, scientific data on the actual quantitative relationship between visual hide cleanliness and microbial (particularly pathogen) loads on corresponding bovine carcasses are limited, and those that exist are often contradictory (Antic et al., 2010; Byrne et al., 2000; Gill, 2004; McEvoy et al., 2000; Ridell and Korkeala, 1993; Van Donkersgoed et al., 1997). The recent results from Hauge et al. (2012) showed that several factors affected the cattle hide cleanliness on-farm, and there were also identified some differences in affecting factors between herds producing dirty animals for slaughter and those presenting only clean cattle for slaughter. Frequently, clipping of hides was one of the most effective ways of improving cattle visual cleanliness. Nevertheless, in another study, clipping of hides – although improving the visual cleanliness - did not produce significant decontamination effects on the microorganisms present on hides (Small et al., 2004), but removal of dirt may reduce the

transferability of microorganisms from hide onto the meat. At dressing, the categorisation of visual cleanliness of cattle presented for slaughter correlated with the actual measured level of microbial contamination of carcasses (Blagojevic et al., 2012a; Hauge et al., 2012). One possible explanation for those between-studies conflicting findings is the fact that significant differences exist in slaughter hygiene procedures, speed of slaughter, facility design, sanitation effectiveness and worker practices in different slaughterhouses (Sofos and Smith, 1998; Sofos, 2005). All these factors contribute to carcass contamination and hence can interfere with the relationship between hide contamination and dressed carcass contamination.

1.2. Prevention and/or reduction of pathogen spread during lairaging

As described in detail in point 6 of Annex B, transport and lairaging lead to increased faecal shedding and/or levels of food-borne pathogens in animals. The general issues and control measures presented in that section can be extrapolated to the lairaging situation (e.g. preventing mixing of batches, shorter lairage times).

1.3. Hygiene of dressing of slaughtered bovine animals

Overall, during carcass dressing, microorganisms are transferred from the hide and gastrointestinal tract to the carcass directly by contact with the hide or gut spillage, or indirectly via contaminated hands, knives, other equipment and the air. During dehiding (i.e. skinning) of slaughtered animals, a range of control measures are used e.g. frequent sterilization of knives, not alternating hands holding the hide and the knife, cutting the skin inside-out ('spear-cut'), preventing touching of the meat with the freed skin ('hide inrolling'), minimizing the creation of aerosols, and using mechanical dehiding technologies ('hide pullers'; downward pullers are more hygienic than upward pullers) rather than manual dehiding. During evisceration the abdominal cavity is opened using a knife and the connective tissue joining the bung and the viscera to the carcass is cut. 'Rodding' (sealing the oesophagus with a crocodile clip, plastic ring or starch cone) may be performed to prevent leakage. The spread of faecal material from the rectum can be prevented or reduced by bagging and tying the bung.

Dehiding and evisceration are commonly designated as CCPs for most relevant hazards as part of the HACCP plan. The critical limit for both is zero visible faecal contamination on the resultant carcasses, and achieving the limit must be monitored. Currently, monitoring of faecal contamination on every carcass is done twice i.e. by both the operator and the official authority. The former is done as a part of HACCP procedures related to dehiding and evisceration CCPs, whilst the latter is done at the end of the slaughter-line during the *post-mortem* inspection (where carcass decontamination is only applied after this inspection is successful). This faecal contamination monitoring is based on visual inspection, but it may be facilitated using an online monitoring system (Tergney and Bolton, 2006). When faeces or faecal stains are detected, they are immediately removed by trimming. In the USA, faecal stains can also be steam-vacuuming if the soil spots do not exceed 2.5 cm in diameter. Cause of breach in hygiene should be investigated, the relevant procedures reviewed and the secondary corrective actions may require modifications of the procedure, retraining of personnel, replacement of knives, and similar. Significant reductions in carcass contamination due to trimming have been shown in studies where the operatives were instructed to immerse their knives and hooks in water at 82°C or higher prior to touching the carcass (Kochevar et al., 1997; Prasai et al., 1995; Reagan et al., 1996); the double knife concept is particularly effective as it forces the worker to allow the knife enough time in hot water while the other knife is being used. In contrast, some studies reported no effect on carcass contamination (Gill et al., 1996; Miller et al., 1995). However, in the latter studies the operatives were not instructed to immerse their knives and hooks prior to use. Another study, by Tergney and Bolton (2006), suggested that monitoring and trimming could reduce the incidence of faecal contamination as a result of both dehiding and evisceration by up to 50%, but only if the anatomical site of contamination was related to a causative operation and preventative corrective action was applied.

2. Decontamination treatments

It has been widely recognised that certain microbial contamination (including with main hazards *Salmonella* spp. and pathogenic VTEC) is transferred to bovine carcasses during slaughter and dressing processes, even when conducted under best hygiene conditions; it is unavoidable – and more so when incoming contamination from bovine animals is higher. In situations where pre-set *Salmonella* spp. and pathogenic VTEC targets for chilled bovine carcasses are uncertain or not achieved consistently in spite of using appropriate technologies and following process hygiene-based measures, additional measures, based on effective antimicrobial (decontamination) treatments of carcasses can be considered and used. However, these treatments should not be a substitute for, but only in addition to, process hygiene-based measures. Should the carcass decontamination treatments aimed at *Salmonella* spp. and pathogenic VTEC elimination/reduction be used in the slaughterhouse, their application parameters must be specified and their effectiveness subjected to appropriate validation, monitoring and verification within a HACCP-based plan. Currently in the EU, use of antimicrobial treatments in bovine slaughterhouses is possible, subject to assessment and approval of each treatment by the official authority after submission of the operator's application with data on its efficacy, safety and technical specifications (EFSA Panel on Biological Hazards, 2010b). In some other countries e.g. USA, antimicrobial treatments of carcasses are routinely used in bovine slaughterhouses as a part of the HACCP plan as well as of official meat inspection procedure.

A range of specific interventions can be applied targeting enteric pathogens such as VTEC and *Salmonella* spp. either on hides, or on dressed carcasses, or both (Sofos, 2005). In some countries e.g. USA, antimicrobial treatments of hides (Loretz et al., 2011) are often applied on animals post-bleeding but pre-skinning; such interventions have not been used under commercial conditions in the EU to date. Research studies indicated that such treatments of hides aimed either at killing of bacteria on the hair (Arthur et al., 2007) or at immobilizing/fixing those on the hair (Antic et al., 2011) can significantly reduce hide-to-meat transfer of microbial contamination, including pathogenic VTEC and *Salmonella* spp (Buncic and Sofos, 2012). Antimicrobial treatments of dressed carcasses include application of organic acids, steam pasteurisation and hot water washing. The application of acetic acid to beef hides reduced *E. coli* O157 counts by 0.7 to 2.1 $\log_{10}$ CFU/cm^2 and *Salmonella* spp. by 2.4 to 4.8 $\log_{10}$ CFU/cm^2 (Carlson et al., 2008; Mies et al., 2004). Corresponding reductions achieved with lactic acid sprays are 2.9 to 4.3 $\log_{10}$ CFU/cm^2 and 1.3 to 5.5 $\log_{10}$ CFU/cm^2, respectively (Carlson et al., 2008; Mies et al., 2004). Steam treatments reduced inoculated *E. coli* O157 hide counts by 4.2 to 6.0 $\log_{10}$ CFU/cm^2 (McEvoy et al., 2006) and *Salmonella* counts on carcasses by < 0.7 to 4.8 $\log_{10}$ CFU/cm^2 (Phebus et al., 1997; Retzlaff et al., 2005). Hot water at 72 °C to 85 °C achieves a 1.0 to 2.8 $\log_{10}$ CFU/cm^2 reduction in *Salmonella* spp. on beef carcasses (Arthur et al., 2008; Cutter and Rivera-Betancourt, 2000; Kalchayanand et al., 2009). Where antimicrobial treatments (decontamination) of carcasses are used, they are normally managed as CCPs within the HACCP programme.

3. Carcass chilling

Dressed carcasses are mandatorily subjected to chilling (to achieve < 7 ^{o}C in meat immediately following slaughter, with a constant decline in the temperature curve) normally conducted by cold air circulation, aimed at prevention or reduction of the multiplication of microbial hazards. Both pathogenic VTEC and *Salmonella* spp. are unable to grow at those temperatures, hence carcass chilling is commonly considered as a CCP within HACCP programmes.

4. Control options related to meat inspection-mediated cross-contamination

During manual handling of carcasses and organs along the slaughterline, microbial cross-contamination can be transferred via hands and cutting equipment/tools (e.g. knives) between organs, between organs and carcasses and/or between carcasses. Manual handling-mediated cross-contamination can occur not only during dressing procedures, but also during some other routine

operations applied to every slaughtered bovine, such as *post-mortem* inspection, trimming, and grading. Most theoretical considerations and experimental studies on the role of manual techniques (palpation, incision) used during *post-mortem* meat inspection in microbial cross-contamination of meat at slaughterhouses have been focused on pig slaughter, whist those looking at this issue at ruminant slaughter have been more seldom. Details are presented in Section 5.3 in the main body of this Appendix.

Thus, omission of these manual techniques and conducting visual-only meat inspection is proposed for *post-mortem* inspection of routine slaughter of bovine animals. It is not proposed for *post-mortem* inspection of bovine animals processed outside routine slaughter i.e. those suspected when assessing FCI, at *ante-mortem* or *post-mortem* inspection to be diseased or to have a condition that may adversely affect human or animal health ('suspect bovine animals'). These animals should continue to be slaughtered separately from routine slaughter and subjected to detailed *ante-mortem* and *post-mortem* examinations separately from the slaughterline operation, where appropriate, and including laboratory testing if necessary.

5. Management of microbial risks within slaughterhouse operation

Hygienic slaughter is based on the application of prerequisite programmes including GMP and GHP, which constitute the foundation for implementation of HACCP programmes. Additional control activities are then implemented within the HACCP framework to prevent, reduce or eliminate most relevant hazards such as pathogenic VTEC and *Salmonella* spp. GMP describes the requirements for hygienic design and construction of premises and equipment. It is a combination of quality and operating procedures aimed at ensuring that carcasses are consistently produced to the required microbiological standard. GHP describes the basic hygienic measures including cleaning and sanitation. Furthermore, it is generally accepted that HACCP is the most effective means of preventing and/or reducing food safety risks associated with bovine meat, and Regulations (EC) No 852/2004 and No 853/2004 mandate implementation of HACCP. In the bovine slaughterhouse, HACCP is applied to control the most important hazards that are not sufficiently controlled solely by the general/universal measures within the prerequisite programme i.e. for which the GMP/GHP alone cannot reliably ensure the elimination or the expected reduction of the high-priority hazards. Unlike the general nature of the GMP/GHP-based controls, controls within the HACCP program are operator-, product- and hazard-specific. Microbiological testing is a necessary part of HACCP and is used to validate critical control points to ensure that actions taken at these points are sufficient to achieve the reduction stated in the HACCP plan. Ongoing verification that the HACCP system is working also requires microbiological testing.

Regulation (EC) No 852/2004 also requires FBOs to comply with microbiological criteria for foodstuffs. These microbiological criteria are laid down in Commission Regulation (EC) No 2073/200 (the annex of which was updated in Regulation (EC) No 1441/2007). FBOs must ensure that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the PHC are met and that the food safety criteria (FSC) applicable throughout the shelf life of the products can be met under reasonably foreseeable conditions of distribution, storage and use. They are required to take corrective action if the criteria are not met. FBOs must also comply with the implementing rules laid down in the Regulation.

ABBREVIATIONS

bTB	bovine tuberculosis
CAC	Codex Alimentarius Commission
CFU	colony forming units
DALY(s)	Disability-adjusted life year(s)
DFD	dark, firm and dry
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFSA	European Food Safety Authority
ESBL/AmpC	extended spectrum and/or AmpC β-lactamases
EU	European Union
FBO	food business operator
FCI	food chain information
GHP	good hygiene practice
GFP	good farming practice
GMP	good manufacturing practice
HACCP	Hazard Analysis and Critical Control Point
HEI	harmonised epidemiological indicator
ICMSF	International Committee on Microbiological Specifications for Foods
MAP	*Mycobacterium avium* subspecies *paratuberculosis*
MDR	Multi-drug resistant
MS(s)	Member State(s)
PCR	polymerase chain reaction
PHA	process hygiene assessment
PHC	process hygiene criteria
PSE	pale, soft and exudative
TESSy	The European Surveillance System
QA	quality assurance
TVC	total viable count
VTEC	verocytotoxin-producing *Escherichia coli*

Appendix B: Assessment on chemical hazards

SUMMARY

Meat inspection in the EU is specified in Regulation (EC) No 854/2004. The main objective of meat inspection is to ensure that meat is fit for human consumption. Historically, meat inspection procedures have been designed to control slaughter animals for the absence of infectious diseases, with special emphasis on zoonoses and notifiable diseases. The mandate that meat needs to be fit for human consumption, however, includes also the control of chemical residues and contaminants that could be potentially harmful for consumers. This aspect is not fully addressed by the current procedures.

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) was asked to identify and rank undesirable or harmful chemical residues and contaminants in bovine animals. Such substances may occur as residues in edible tissues from the exposure of bovine animals to contaminants in feed materials as well as following the possible application of non-authorized substances and the application of authorized veterinary medicinal products and feed additives. A multi-step approach was used for the ranking of these substances into categories of potential concern. As a first step, the CONTAM Panel considered substances listed in Council Directive 96/23/EC and evaluated the outcome of the National Residue Control Plans (NRCPs) for the period 2005–2010. The CONTAM Panel noted that only 0.25 % of the total number of results were non-compliant for one or more substances listed in Council Directive 96/23/EC. Potentially higher exposure of consumers to these substances from bovine meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedures. The available aggregated data indicate the number of samples that were non-compliant with the current legislation. However, in the absence of substance-specific information, such as the tissues used for residue analysis and the actual concentration of a residue or contaminant measured, these data do not allow for a reliable assessment of consumer exposure. Independently from the occurrence data reported from the NRCPs, other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that are found in other testing programmes, that bioaccumulate in the food chain, substances with a toxicological profile of concern, and the likelihood that a substance under consideration will occur in bovine carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as of high, medium, low and negligible potential concern.

The terms of reference from the European Commission requested two opinions, one covering bovine animals under six weeks old and the other covering bovine animals over six weeks old. However, the available data from the NRCPs do not readily discriminate between the two age groups. Therefore, the CONTAM Panel has not differentiated between these two age groups in terms of chemical residues and contaminants.

Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern owing to their known bioaccumulation in the food chain, the risk of exceedance of maximum levels (MLs), and in consideration of their toxicological profile.

The following substances were ranked in the category of medium potential concern: stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones and beta-agonists (especially clenbuterol) because of their toxicity for humans, their efficacy as growth promoters in cattle and the incidence of non-compliant results; chloramphenicol and nitrofurans because they have proven toxicity for humans, are effective as antibacterial treatments for cattle and residues in bovine carcasses have been found from the NRCPs in various MSs; non dioxin-like polychlorinated biphenyls (NDL-PCBs) because, while they bioaccumulate and there is a risk for exceedance of the MLs, they are less toxic than dioxins and DL-PCBs; and the chemical elements cadmium, lead and mercury because of the number of non-compliant results reported under the NRCPs and their toxicological profile.

Residues originating from other substances listed in Council Directive 96/23/EC were ranked as of low or negligible potential concern.

The CONTAM Panel emphasises that this ranking into specific categories of potential concern is based on the current knowledge regarding toxicological profiles, usage in bovine animal production and occurrence as chemical residues and contaminants. Where changes in any of these factors occur, the ranking might need amendment.

In addition to the ranking of chemical residues and contaminants in bovine animals, the CONTAM Panel was asked to assess the main strengths and weaknesses of current meat inspection protocols within the context of chemical hazards. It was noted that current procedures for sampling and testing are, in general, well established and coordinated, including follow-up actions subsequent to the identification of non-compliant samples. In addition, the identification system for bovine animals provides full transparency of the EU bovine stock and the current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring. The regular sampling and testing for chemical residues and contaminants is an important disincentive for the development of undesirable practices and the prescriptive sampling system allows for equivalence in the control of EU veal/beef. Nevertheless, a major weakness is that, with very few exceptions, the presence of chemical hazards cannot be identified by current ante-/*post-mortem* meat inspection procedures at the slaughterhouse level, and there is a lack of sufficient cost-effective and reliable screening methods. In addition, sampling is mostly prescriptive rather than risk or information based. There is limited ongoing adaptation of the sampling and testing programmes to the results of the residue monitoring programmes, with poor integration between the testing of feed materials for undesirable substances and the NRCPs and sampling under the NRCPs, which reflect only a part of testing done by a number of MSs, the results of which should be taken into consideration.

The CONTAM Panel was also asked to identify and recommend inspection methods for new hazards. As dioxins and DL-PCBs have not yet been comprehensively covered by the sampling plans of the current meat inspection, they should be considered as 'new' hazards as they have been ranked as being of high potential concern. Moreover, for other organic contaminants that may accumulate in food-producing animals and for a number of chemical elements used as feed supplements, only limited data regarding residues in bovine animals are available. This is the case, in particular, for brominated flame retardants, including polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), as well as perfluorinated compounds (PFCs) including (but not limited to) perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

The CONTAM Panel concludes that the types and likelihood of occurrence of chemical residues and contaminants in bovine animals vary due to the diversity of bovine farming in the EU. The CONTAM Panel recommends that future monitoring programmes should be based on the risk of occurrence of chemical residues and contaminants, taking into account the completeness and quality of the FCI supplied and the ranking of chemical compounds into categories of potential concern, which ranking needs to be regularly updated. Control programmes for chemical residues and contaminants should be less prescriptive, with sufficient flexibility to adapt to results of testing, and should also include 'new hazards'. There is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants. The development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into the residue control programmes. For prohibited substances, testing should be directed where appropriate towards the farm level and, in the case of substances that might be used illicitly for growth promotion, control measures, including testing, need to be refocused to better identify the extent of abuse in the EU.

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ASSESSMENT OF CURRENT MEAT INSPECTION PROTOCOLS FOR THE IDENTIFICATION OF CHEMICAL SUBSTANCES OF POTENTIAL CONCERN THAT MAY OCCUR AS RESIDUES OR CONTAMINANTS IN BOVINE ANIMALS

1. Introduction

Meat inspection in the EU is specified in Regulation (EC) No 854/2004[1]. The main objective of meat inspection is to ensure that meat is fit for human consumption. Historically, meat inspection procedures have been designed to control slaughter animals for the absence of infectious diseases, with special emphasis on zoonoses and notifiable diseases. The mandate that meat needs to be fit for human consumption, however, also includes the control of chemical residues and contaminants in meat that could be potentially harmful for consumers. This aspect is not fully addressed by the current procedures. For the purposes of this document, 'chemical residues' refer to chemical compounds which result from the intentional administration of legal or illegal pharmacologically active substances while 'chemical contaminants' refer to chemical compounds originating from the environment.

This document aims to identify undesirable or harmful chemical residues and contaminants that may occur in bovine animals taking into account the current legislation and the results from the National Residue Control Plans (NRCPs), implemented in line with Council Directive 96/23/EC.[2] These findings, together with the characteristics of the individual substances and the likelihood that a substance will occur in meat from bovine animals, were used to rank chemical residues and contaminants into categories of potential concern. Four categories were established, constituting a high, medium, low or negligible potential concern. In the second part, the main strengths and weaknesses of current meat inspection protocols were assessed within the context of chemical hazards. The ultimate aim is an overall evaluation of the current strategies for sampling and analytical testing, resulting in recommendations for possible amendments to the current meat inspection protocols.

The terms of reference (TORs) requested the delivery of two opinions, one covering bovine animals under six weeks old and the other covering bovines over six weeks old. However, the available data from the NRCPs do not readily discriminate between the two age groups. Therefore, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) decided that it was not necessary to differentiate between these two age groups in terms of chemical residues and contaminants.

In this opinion, where reference is made to European legislation (regulations, directives, decisions), the reference should be understood as relating to the most current amendment, unless otherwise stated.

1.1. Definition of bovine animals presented for slaughter

Section IV of Council Regulation 854/2004 establishes the specific requirements for *post-mortem* inspection of domestic bovine animals under six weeks old and over six weeks old. Stricter inspection protocols are applied to bovine animals over six weeks old. The differences in inspection protocols are related to a requirement for more invasive (i.e. beyond visual) inspection for bovine animals over six weeks old. Animals under six weeks old are pre-ruminants and, therefore, are likely to consume essentially milk or milk replacers. It should be noted that milk for human consumption from bovine animals is not covered in this opinion.

Bovine animals farmed within the EU are of the subfamily Bovinae and tribe Bovini, with 99.5 % of these animals being domestic cattle (*Bos taurus*) and approximately 0.5 % being buffalo (*Bubalus bubalis*). Other bovine animals, such as bison (*Bison bison*), are not yet farmed at a level of

[1] Regulation (EC) No 854/2004 of the European Parliament and of the Council of 30 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. OJ L 139, 30.4.2004, p. 206. Corrigendum, OJ L 226, 25.6.2004, p. 83.

[2] Council Directive 96/23/EC of 29 April 1996 to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. OJ L 125, 23.5.96, p. 10–32.

commercial significance within the EU. Data from Eurostat on bovine animal production (which includes cattle and buffalo production) in the EU are presented in Table 1. Data on production figures for bison have not been identified owing to the low scale of production.

Table 1: Production figures for cattle and buffalo in the EU-27[a] from 2002 to 2010. Data source: Statistical database of Eurostat, Agriculture, Agricultural products, Animal Production, Livestock, Cattle population. Units: 1 000 head (animals).

	2010	2009	2008	2007	2006	2005	2004	2003	2002
Cattle	86 222.4	88 294.1	88 884.2	88 701.0	88 182.7	89 381.7	89 967.7	90 891.2	92 143.7
Buffalo[b]	406.2	389.2	351.5	336.2	280.4	259.0	251.8	231.3	192.5
Total	86 628.6	88 683.3	89 235.7	89 037.2	88 463.1	89 640.7	90 219.5	91 122.5	92 336.2

[a] EU-27, data from the current 27 Member States (MSs) were included for all years.
[b] Buffalo production is only reported by five MSs in the given period (2002–2010). One MS produces close to 90 % of all buffalo reared in the EU.

Based on the production volumes for these animal categories and the relatively low European production of buffalo, the present document is focused on the likelihood of chemical residues and contaminants being present in cattle.

1.2. Categories of cattle production

Bovine farming in the EU is diverse, with many differences between intensive and extensive production as well as between veal calves and adult bovine animals. For the purposes of this opinion, intensive farming applies to animals housed throughout their productive life and fed with compound feed (often supplemented with roughage and concentrates) while extensive farming applies to animals primarily kept outdoors at pasture.

1.2.1. Veal production

Veal production relates to the production of meat from calves, normally male calves from the dairy herd that are reared in specialised fattening units. Typically, veal calves are placed in fattening units at about two weeks of age and are slaughtered at between five and seven months of age. In accordance with Council Directive 2008/119/EC,[3] the traditional practice of rearing veal calves in individual crates has been prohibited in the EU for animals over eight weeks of age. Veal calf production is mainly in pens with wooden or concrete slatted floors containing small groups (four to seven) of calves, with a minority of production being in large groups (30–60 animals). EU Directive 2008/119/EC specifies minimum standards for the protection of veal calves, for example animal weight/size, ventilation systems and air supply.

For feeding, milk replacer is administered manually or by automated feeding in individual buckets or in a common trough, while solid feeds are provided from a trough. Regular regrouping of calves during the fattening period is required to ensure a homogeneous growth rate within the group. According to Council Directive 91/629/EEC,[4] amended by Commission Decision 97/182/EC,[5] calves over two weeks old should receive, in addition to milk replacer, fibrous feed to promote normal development of the rumen and rumen motility. Low iron in the diet, also copper, produces the pale

[3] Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (Codified version). OJ L 10, 15.1.2009, p. 7–13.
[4] Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves. OJ L 340, 11.12.1991, pp. 28–32.
[5] 97/182/EC: Commission Decision of 24 February 1997 amending the Annex to Directive 91/629/EEC laying down minimum standards for the protection of calves. OJ L 76, 18.3.1997, pp. 30–31.

colour of veal; the same directive specifies a minimum blood haemoglobin level to achieve the desired meat colour while guaranteeing calf health.

Veal calf production occurs on a larger scale in a small number of MSs (EFSA, 2012a). Such farms often operate under the standards of Good Farming Practice (GFP) and Good Hygiene Practice (GHP) and with HACCP-based protocols in place, providing detailed Food Chain Information (FCI). FCI is the animal's life history data from birth, through all stages of rearing, up to the day of slaughter. In particular, the food business operator at the slaughterhouse should receive information related to the veterinary medicinal products (VMPs) or other treatments administered to the animals within a relevant period prior to slaughter, together with their administration dates and their withdrawal periods. Moreover, any test results for samples taken from the animals within the framework of monitoring and control of residues should also be communicated to the slaughterhouse operators before the arrival of the animals.

'Pink veal', also called 'rosé veal', differs from conventional veal production in that the calves are reared for a longer period and they receive larger amounts of solid feed with no iron restriction. Initially, these calves are fed milk or milk replacer and, after weaning, are fed a diet of forage and concentrates. The calves have normal haemoglobin levels and the meat has a darker 'pink' colour. The calves are slaughtered at between 5 and 8 months of age or as 'baby beef' at between 8 and 11 months of age.

In some situations, male calves originating from dairy farms may be slaughtered at a younger age, such as less than one month old. These calves are known by various names, such as 'baby calves' or 'suckling calves'.

1.2.2. Beef production

Across the EU, beef is produced in a variety of different systems depending on such factors as climatic conditions, agronomy, farm size and farming tradition. There are two main types of beef production, one which is largely extensive pasture-based and the other that is largely intensive cereal-based. The animals for beef production come from two sources, either as calves from dairy herds or as calves from beef suckler cows. A substantial number of calves from dairy herds also go to veal production, which predominates in some MSs.

Calves from dairy herds are typically removed from the cows after a number of days and reared on milk or milk replacer for a number of weeks, after which they are weaned and become functional ruminants, depending on a diet of forage and/or concentrates. In contrast, calves from beef suckler herds typically remain with the cow for six to nine months before they are weaned and transferred to a forage diet. In both cases, after weaning the calves are placed in various beef fattening systems.

Female calves are raised as heifers. Male calves may be raised for beef either as intact animals (bulls) or as castrates (steers or bullocks). Male calves are raised predominantly as steers in Ireland and the United Kingdom and, to a lesser extent, in France, reflecting grass-based grazing systems. In all other EU MSs producing beef animals, male calves are raised predominantly or exclusively as bulls.

Beef production systems may be grass based with extensive grazing periods (seven months) throughout the year and shorter periods of overwintering (five months) in housing on a diet mainly of hay or grass silage, supplemented with protein concentrates and vitamins/minerals. Such systems are used primarily for steers and heifers from dairy or beef suckler herds and typically deliver animals for slaughter at 20–24 months of age, after the winter feeding period. Alternatively, steers and heifers may be overwintered during the second year on grass silage and finished on grazing, going to slaughter at approximately 30 months of age.

Beef production systems for bulls from the dairy or beef suckler herds are based typically on grass silage or on maize silage, depending on region, supplemented with protein concentrates and

vitamins/minerals. These systems deliver animals for slaughter at 16–18 months of age. Alternatively, bulls may be produced using a cereal diet with animals ready for slaughter at 12–15 months of age.

In addition to young animals reared specifically for beef production, cows from dairy herds and from beef suckler herds are slaughtered at the end of their productive life (cull cows) and represent a substantial proportion of beef entering the food market. Because of the age of these animals at slaughter, much of the meat from cull cows may be used in manufacturing of meat products. To a lesser extent, another source of meat are bulls slaughtered following their use in breeding.

1.2.3. Buffalo production

Buffaloes are animals of the tropics and subtropics. Worldwide, approximately 168 million head may be found, most of them in Asia, with some 500 000 animals in Europe (Borghese and Mazzi, 2005). In all, the Mediterranean area harbours about 5.5 million head and, in the EU, they are found mainly in Italy, Romania, Bulgaria and Greece. However, buffaloes are kept also in moderate climates in some countries, e.g. Germany (Borghese, 2009). They are kept indoors at night and outdoors within fenced areas, i.e. paddocks, being fed, like dairy cows, on a diet of maize silage, concentrates, hay and straw (Borghese and Mazzi, 2005). Buffalo meat occurs primarily as a by-product of dairy production, in which buffalo milk is used to make specialised products, particularly mozzarella cheese.

The CONTAM Panel noted the emerging literature indicating that significant differences between cattle and buffalo exist in areas such as pharmaco- and toxicokinetics of several compounds and related physiological parameters (Knox et al., 1994; Raipuria et al., 2007; Motawee et al., 2009; Genualdo et al., 2011). Although variations in the excretion profiles of a number of chemical substances in milk and milk products between the two species have been reported, the available data do not allow for any conclusion as to the practical importance of such differences for residues and contaminants in buffalo meat.

1.3. Procedures in the current meat inspection of bovine animals

Council Regulation (EC) No 854/2004 prescribes that each bovine animal presented for slaughter has to be inspected *ante*- and *post*-mortem. Historically, and still of most importance, inspection in its current form focuses mainly on diseases, and tuberculosis has very much influenced the procedures used. Bovine inspection procedures consider the individual animals as inspection units. This is reflected also in the mandatory identification and registration of individual animals via an ear-tagging and animal passport system, as well as computerised databases.

1.3.1. *Ante-mortem* inspection and food chain information

Visual *ante-mortem* inspection is carried out at the level of the individual animal. In contrast to poultry and fattening pigs, FCI for bovine animals varies depending on the animal category. For example, veal calves may be presented for slaughter as a large group with common FCI while adult animals may be presented for slaughter in small numbers or even as individuals. The extended life of some of these animals, including periods raised on pasture, may preclude reliable and verifiable lifetime FCI.

Ante-mortem inspection consists of a general clinical investigation. It focuses primarily on clinical signs of disease suggesting systemic infections (e.g. fever, coughing, nasal discharge, respiratory distress, diarrhoea) or other conditions (e.g. traumatic injuries, joint and musculoskeletal inflammations) that might suggest the use of VMPs potentially without observing the prescribed withdrawal periods.

Ante-mortem inspection may also include observation of clinical signs that may point to illegal treatments for growth-promoting purposes (Serratosa et al., 2006). In addition to a general change in carcass conformation, amongst the clinical signs which may indicate potential use of these substances, the most relevant are the following:

- Marked hypertrophy of the hindquarters in breeds not specialised for meat production along with a reduction in fat depots in the tail region, increased heart and respiratory frequencies, fever, hyperexcitability and abnormal reactions to external stimuli are suggestive of a treatment with beta-agonists (Brockway et al., 1987).
- Gynaecomastia and hypogonadism in male calves, oedema of the vulva and abnormal development of the mammary gland in prepubertal female calves have been associated with the administration of oestrogenic compounds (Biolatti, 2009).
- Haemorrhagic diarrhoea and polyuria may indicate the illicit use of corticosteroids (Anonymous, 2008).

However, clinical signs indicating misuse or abuse of pharmacologically active substances are, in many cases, not expected to be clearly observable.

1.3.2. *Post-mortem* inspection

Based on Regulation (EC) No 854/2004, *post-mortem* inspection was, and still is, directed primarily at the detection of lesions due to infections, based on observation, palpation and incision. An exception is the mandatory sampling for BSE/TSE specified for animals of a certain age, which is outside the remit of this mandate.

Visual inspection of the carcass (and offal) may , in some cases, allow for the identification of gross alterations in carcass conformation and organ-specific lesions in lungs, kidneys, liver or other organs that may be indicative of recent use of VMPs (with the possibility of non-compliance with withdrawal periods) or acute or chronic exposure to toxic substances. This aspect is not covered in detail in the current meat inspection protocols. However, in most cases, exposure to chemical compounds, including substances that accumulate in the body (toxic elements, certain organic pollutants), does not result in typical organ lesions. Hence, it needs to be considered that evidence for the presence of chemical residues and contaminants will not, in most cases, be apparent during the current inspection of bovine carcasses and organs. Therefore, the meat inspection approach based on 'detect and immediately eliminate', used for biotic (microbiological) hazards in slaughterhouses, is generally not applicable to abiotic hazards.

Nonetheless, certain gross alterations may be indicative of exposure to illegal growth promoters or the abuse of certain VMPs (e.g. glucocorticoids) for growth-promoting purposes. The most relevant are the following (Serratosa et al., 2006):

- A marked decrease in subcutaneous fat thickness and in both pericardial and perirenal fat, along with disappearance (veal calves) or smoothing (beef cattle) of the tracheal crest and dark discoloration of the liver, may be associated with beta-agonist treatment.
- Testicular hypoplasia or uterus enlargement, mucometra and the occurrence of either atrophied or macro- or microcystic ovaries may be suggestive of treatments with estrogenic or androgenic compounds, especially in veal calves.
- Thymus hypotrophy or atrophy in veal calves, together with bladders full of urine in several animals from the same production unit, may be indicative of glucocorticoid abuse.
- Thyroid enlargement may reflect exposure to thyreostatic agents.

As with *ante-mortem* inspection, however, such alterations in organs and carcasses may not be, in many cases, be indicative of misuse or abuse of pharmacologically active substances.

While monitoring programmes (Council Directive 96/23/EC, which is fully described in Section 1.4) may provide a gross indication of the prevalence of undesirable chemical residues and contaminants in

bovine carcasses, the sole intervention at slaughterhouse level is the isolation of a suspect carcass as potentially unfit for human consumption, pending results of residue testing.

1.4. Current legislation

Council Directive 96/23/EC prescribes the measures to monitor certain substances and residues thereof in live animals and animal products. It requires that MSs adopt and implement a national residue monitoring plan, also referred to as the NRCP, for defined groups of substances.[6] MSs must assign the task of coordinating the implementation of the controls to a central public body. This public body is responsible for drawing up the national plan, coordinating the activities of the central and regional bodies responsible for monitoring the various residues, collecting the data and sending the results of the surveys undertaken to the Commission each year.

The NRCP should be targeted; samples should be taken on-farm and at slaughterhouse level with the aim of detecting illegal treatment or controlling compliance with the maximum residue limits (MRLs) for VMPs according to the Commission Regulation (EU) No 37/2010,[7] with the maximum residue levels for pesticides as set out in Regulation (EC) No 396/2005,[8] or with the maximum levels (MLs) for contaminants as laid down in Commission Regulation (EC) No 1881/2006.[9] This means that in the NRCPs, the MSs target the groups of animals/gender/age combinations where the probability of finding residues is the highest. This approach differs from random sampling, where the objective is to gather statistically representative data, for instance to evaluate consumer exposure to a specific substance.

The minimum number of bovine animals to be controlled each year for all kinds of residues and substances must be at least equal to 0.4 % of bovine animals slaughtered the previous year. The following breakdown must be respected in the national sampling plans (further details on Group A and B compounds is presented in Section 2.1):

- Group A[10]: 0.25 % of bovine animals slaughtered the previous year, which should be divided as follows:
  - half of the samples are to be taken from live animals on the holding (by derogation, 25 % of samples analysed for the research of Group A 5 substances (beta-agonists) can be taken from appropriate material such as feedingstuffs, drinking water, etc.);
  - half of the samples are to be taken at the slaughterhouse.

Each subgroup of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A. The balance must be allocated according to the experience and background information of the MS.

- Group B: 0.15 % of the total bovine animals slaughtered the previous year, with the following breakdown:
  - 30 % must be checked for Group B1 substances;

[6] Commission Staff Working Document on the Implementation of National Residue Monitoring Plans in the Member States in 2009 (Council Directive 96/23/EC).
[7] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1–72.
[8] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue level of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
[9] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, pp. 5–24.
[10] See section 2.1 for a detailed description of Group A and B as defined by the Council Directive 96/23/EC.

– 30 % must be checked for Group B2 substances;
– 10 % must be checked for Group B3 substances.

The balance must be allocated according to the situation of the MS.

In the case of imports from third countries, Chapter VI of Council Directive 96/23/EC describes the system to be followed to ensure an equivalent level of control on such imports. In particular, it specifies (a) that each Third Country must provide a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to the Directive, (b) that such guarantees must have an effect at least equivalent to those provided for in Council Directive 96/23/EC, (c) that compliance with the requirements of and adherence to the guarantees offered by the plans submitted by Third Countries shall be verified by means of the checks referred to in Article 5 of Council Directive 72/462/EEC[11] and the checks provided for in Council Directives 90/675/EEC[12] and 91/496/EEC[13] and (d) that MSs are required to inform the Commission each year of the results of residue checks carried out on animals and animal products imported from third countries, in accordance with Council Directives 90/675/EEC and 91/496/EEC.

1.5. Actions taken as a consequence of non-compliant results

In accordance with Article 8 of Council Directive 96/23/EC, the MSs are requested, as a follow-up, to provide information on actions taken at regional and national level as a consequence of non-compliant results. The Commission sends a questionnaire to the MSs to obtain an overview of these actions, for example when residues of non-authorised substances are detected or when the MRLs/MLs established in EU legislation are exceeded. The actions taken by the MS may include:

- suspect sampling;
- modifications of the NRCPs;
- other actions taken as a consequence of non-compliant results.

1.5.1. Suspect sampling

Sampling as suspect includes:

- samples taken as a consequence of non-compliant results on targeted samples taken in accordance with the monitoring plan (Article 5 of Council Directive 96/23/EC);
- samples taken as a consequence of possession or presence of prohibited substances at any point during manufacture, storage, distribution or sale throughout the food and feed production chain (Article 11 of Council Directive 96/23/EC);
- samples taken where the veterinarian suspects, or has evidence of, illegal treatment or non-compliance with the withdrawal period for an authorized veterinary medicinal product (Article 24 of Council Directive 96/23/EC).

In summary, this means that the term ‘suspect sample’ applies to a sample taken as a consequence of:

- non-compliant results; and/or
- suspicion of an illegal treatment; and/or

[11] Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries. OJ L 302, 31.12.1972, p. 28–54.
[12] Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries. OJ L 373, 31.12.1990, p. 1–14.
[13] Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC. OJ L 268, 24.9.1991, p. 56–68.

- suspicion of non-compliance with the withdrawal periods.

1.5.2. Modification of the NRCPs

Non-compliant results for a specific substance or group of substances or a specific food commodity should result in intensified controls for this substance/group or food commodity in the plan for the following year.

1.5.3. Other actions

Article 16 and Articles 22–28 of Council Directive 96/23/EC prescribe a series of actions (other than modifications of the residue monitoring plan) to be taken in the case of non-compliant results or infringements to:

- carry out investigations in the farm of origin, such as verification of records and additional sampling;
- hold animals in the farm as a consequence of positive findings;
- slaughter animals in the case of confirmation of illegal treatment and to send them to a rendering plant;
- intensify the controls in the farms where non-compliant results were found;
- impound carcasses at the slaughterhouse when non-compliant results have been found;
- declare the carcasses or products of animal origin unfit for human consumption.

It should be noted that targeted sampling as defined by Council Directive 96/23/EC aims at monitoring certain substances and residues thereof in live animals and animal products across EU MSs. In contrast to monitoring, under suspect sampling, a 'suspect' carcass has to be detained at the slaughterhouse until laboratory results confirm or deny conformity with legislative limits for chemical residues. Based on the test results, the carcass can be declared fit or unfit for human consumption. In the first scenario, the carcass is released into the human food chain whereas in the second case the carcass is disposed of.

1.5.4. Self-monitoring residue testing

In addition to the minimum testing requirements which form part of the NRCPs, Council Directive 96/23/EC also establishes the requisites for self-monitoring and co-responsibility on the part of operators.

In accordance with Article 9, chapter III, of Council Directive 96/23/EC, MSs shall ensure that the owners or persons in charge of the establishment of initial processing of primary products of animal origin (slaughterhouses) take all necessary measures, in particular by carrying out their own checks, to:

- accept only those animals for which the producer is able to guarantee that withdrawal times have been observed;
- satisfy themselves that the farm animals or products brought into the slaughterhouse do not contain residue levels which exceed maximum permitted limits and that they do not contain any trace of prohibited substances or products;

The farmers and the food processing operators (slaughterhouses) must place on the market only:

- animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment;

- animals for which, where authorized products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. TOR 1: Identification, classification and ranking of substances of potential concern

2.1. Identification of substances of potential concern

In the current EU legislation, chemical residues and contaminants in live animals and animal products intended for human consumption are addressed in Council Directive 96/23/EC. Identification and ranking of potential concerns within this chapter includes all chemical compounds listed in this Council Directive. Annex I of Council Directive 96/23/EC groups substances that may be found in animal tissues into two categories:

Group A—Substances having anabolic effect and unauthorized substances

A1. Stilbenes, stilbene derivatives, and their salts and esters

A2. Antithyroid agents

A3. Steroids

A4. Resorcylic acid lactones, including zeranol

A5. Beta-agonists

A6. Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990[14] (repealed by Commission Regulation (EU) No 37/2010[7])

Group B—Veterinary drugs (including unlicensed substances which could be used for veterinary purposes) and contaminants

B1. Antibacterial substances, including sulphonamides, quinolones

B2. Other veterinary drugs

- a) Anthelmintics
- b) Anticoccidials
- c) Carbamates and pyrethroids
- d) Sedatives
- e) Non-steroidal anti-inflammatory drugs (NSAIDs)
- f) Other pharmacologically active substances

B3. Other substances and environmental contaminants

- a) Organochlorine compounds, including polychlorinated biphenyls (PCBs)
- b) Organophosphorus compounds
- c) Chemical elements
- d) Mycotoxins
- e) Dyes
- f) Others

[14] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. OJ L 224, 18.8.90, p. 1–8.

According to Council Directive 96/23/EC, in the case of bovine animals analysis for chemical residues and contaminants for all of the listed substances is required with the exception of B2f—Other pharmacologically active substances, B3e—Dyes and B3f—Others.

2.2. Classification of chemical substances in the food chain

As one of the objectives of this assessment of current meat inspection protocols is the identification of chemical substances of potential concern that may occur as residues or contaminants in bovines, but have not been specifically addressed in Council Directive 96/23/EC, a more general grouping of chemical substances was chosen, resulting in the following three major groups:

- substances that have an anabolic effect and unauthorized substances for use in food-producing animals, corresponding to Group A[15] substances in Council Directive 96/23/EC;
- veterinary drugs, also denoted VMPs, corresponding to Groups B1 and B2 substances in Council Directive 96/23/EC, and
- contaminants, corresponding to Group B3 substances in Council Directive 96/23/EC.

The **first group** of chemicals that may occur in edible tissues as residues are those substances prohibited for use in food-producing animals; these substances correspond largely with Group A substances in Council Directive 96/23/EC. There were different rationales for banning these substances for application to animals and the list of group A substances comprises compounds that are of toxicological concern, including VMPs for which an acceptable daily intake (ADI) could not be established, as well as substances having anabolic effects and pharmacologically active compounds that may alter meat quality and/or affect animal health and welfare.

A **second group** of chemicals that may be a source of residues in animal-derived foods are VMPs (including antibiotics, antiparasitic agents and other pharmacologically active substances) and authorized feed additives used in the health care of domestic animals; these substances correspond largely with Group B1 and B2 substances in Council Directive 96/23/EC. These substances have been subjected to assessment and pre-marketing approval by the Committee for Medicinal Products for Veterinary Use of the European Medicines Agency (EMA) according to Regulation (EU) No 470/2009[16] or are licensed as feed additives following a review of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) of EFSA according to Regulation (EC) No 1831/2003[17]. For all VMPs and feed additives licensed for use in food-producing animals, an ADI is established on the basis of the pharmacological and toxicological profile of the candidate drug/additive. Compounds for which no toxicological ADI can be established are excluded from approval. On the basis of the established ADI, MRLs are derived for the parent drug or its metabolites/derivatives (marker residues) in target tissues and these MRLs (µg/kg tissue) are used to establish compliance. The list of allowed substances is presented as Annex, Table 1 of Commission Regulation (EU) No 37/2010 and in the Community Register of feed additives; it should be noted that for most feed additives listed as allowed for use, no MRL is required.

With regard to antibacterial agents, it is important to state that the ranking of substances of concern in this part of the document considers only toxicological concerns related to the presence of residues. Other aspects, such as the emergence of antimicrobial resistance, are considered by the EFSA Panel on

[15] Unauthorized substances are also referred to as prohibited substances.

[16] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OJ L 152, 16.6.2009, p. 11–22.

[17] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29–43.

Biological Hazards (BIOHAZ Panel) in a separate part of this opinion (see Appendix A of the BIOHAZ Panel).

A **third group** of chemical substances that may occur in edible tissues of bovine animals are contaminants that may enter the animal's body mainly via feed, ingested soil, drinking water, inhalation or direct (skin) contact; these substances include the Group B3 substances in Council Directive 96/23/EC. Feed materials can contain a broad variety of undesirable substances comprising persistent environmental pollutants, toxic metals and other elements as well as natural toxins, including toxic secondary plant metabolites and fungal toxins (mycotoxins). Feed producers have to act in compliance with Commission Directive 2002/32/EC[18], listing the undesirable substances in feed and feed materials and presenting maximum content in feed materials or complete feedingstuffs. In a recent re-assessment of these undesirable substances in animal feeds, the CONTAM Panel re-evaluated the risk related to exposure to these substances for animals. Special attention was given to toxic compounds that accumulate or persist in edible tissues, including meat, or are directly excreted into milk and eggs.

2.2.1. Statutory limits

In order to protect public health, Article 2 of Council Regulation (EEC) No 315/93[19] of 8 February 1993 laying down Community procedures for contaminants in food stipulates that, where necessary, maximum tolerances for specific contaminants shall be established. Subsequently, a number of MLs for various contaminants in different foodstuffs were laid down in the Annex of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting MLs for certain contaminants in foodstuffs, amended by Commission Regulation (EC) No 1259/2011.[20] Regarding bovine animals, MLs were established for lead, cadmium, dioxins,[21] the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) and for the sum of six non dioxin-like PCBs (NDL-PCBs).

[18] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10–21.
[19] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. OJ L 37, 13.2.1993, p. 1–3.
[20] Commission Regulation (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs. OJ L 320, 3.12.2011, pp. 18–23.
[21] The term 'dioxins' used in this opinion refers to the sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs).

Table 2: Contaminants currently regulated in Regulation (EC) No 1881/2006 (as amended) in bovine animals.

Contaminant	MLs	Health-based guidance values/MOE approach	Assessments: Reference
Dioxins and dioxin-like PCBs	*Dioxins* Meat, fat and meat products: 2.5 pg WHO-TEQ/g fat Liver and derived products: 4.5 pg WHO-TEQ/g fat *Dioxins + DL-PCBs* Meat, fat and meat products: 4.0 pg WHO-TEQ/g fat Liver and derived products: 10.0 pg WHO TEQ/g fat	TWI: 14 pg WHO-TEQ/kg b.w.	SCF, 2001
Non dioxin-like PCBs (sum of PCBs 28, 52, 101, 138, 153 and 180)	Meat, fat and meat products: 40 ng/g fat Liver and derived products: 40 ng/g fat	MOE approach	EFSA, 2005a
Cadmium	Meat: 0.050 mg/kg wet weight Liver: 0.50 mg/kg wet weight Kidney: 1.0 mg/kg wet weight	TWI: 2.5 µg/kg b.w.	EFSA, 2009a, 2011c
Lead	Meat: 0.10 mg/kg wet weight Offal: 0.50 mg/kg wet weight	MOE approach	EFSA, 2010b

ML, maximum level; b.w.: body weight; MOE, margin of exposure; TEQ: toxic equivalent; TWI, tolerable weekly intake.
Note: besides the above maximum levels, Regulation (EC) No 1881/2006 also sets MLs for raw milk and dairy products of bovine animals.

Recently, the MLs for dioxins and the sum of dioxins and DL-PCBs in food were reviewed taking into account new data, and amended accordingly. The revised MLs above apply from 1 January 2012. In contrast to the former values, the revised MLs are expressed as toxic equivalents (TEQs) using the WHO-TEF_{2005}s for human risk assessment based on the conclusions of the World Health Organization (WHO)—International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Van den Berg et al., 2006).

In addition to dioxins and the sum of dioxins and DL-PCBs, Regulation EC (No) 1881/2006, amended by Regulation EC (No) 1259/2011, also sets MLs for the sum of the six indicator-PCBs identified by the CONTAM Panel (PCB-28, -52, -101, -138, -153, and -180) (EFSA, 2005a) for various kinds of foodstuffs following the same food categorization as for dioxins and the sum of dioxins and DL-PCBs.

As an early warning tool, the European Commission has set action levels for dioxins and DL-PCBs in food through Commission Recommendation 2011/516/EC[22]. Due to the fact that their sources are generally different, separate action levels for dioxins and DL-PCBs were established. The action levels for dioxins and DL-PCBs in meat and meat products (excluding edible offal) of bovine animals are each 1.75 pg WHO-TEQ/g fat. In cases where levels of dioxins and/or DL-PCBs in excess of the action levels are found, it is recommended that MSs, in cooperation with FBOs, initiate investigations to identify the source of contamination, take measures to reduce or eliminate the source of contamination and check for the presence of NDL-PCBs.

MRLs for certain elements in bovine animals are also laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food

[22] Commission Recommendation of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food. OJ L 218, 24.08.2011, p. 23–25.

and feed of plant and animal origin, (originally specified for the use of copper-containing and mercury-containing compounds as pesticides). For copper, the maximum residue levels are each 5 mg/kg for meat and fat and 30 mg/kg each for liver, kidney and edible offal. For mercury compounds (sum of mercury compounds expressed as mercury), the maximum residue levels are 0.01 mg/kg each for meat, fat, liver, kidney and edible offal.

2.3. Ranking of the substances of potential concern

A multi-step approach was used to rank potential concern of the three groups of substances that are presented in Sections 2.1 and 2.2. The steps are:

- evaluation of the outcomes of the NRCPs indicating the number of results that are non-compliant with the current legislation;
- evaluation of the likelihood that specific residues or contaminants, including 'new hazards' (see Section 2.3.5.5), may be present in bovine carcasses;
- consideration of the toxicological profile for chemical substances.

2.3.1. Outcome of the NRCPs within the EU

Data from the NRCPs are published annually and these data were considered as the first step for hazard ranking. Aggregated data for the outcome of the NRCPs for targeted sampling of bovine animals from 2005 to 2010 are presented in Tables 3–5. The grouping follows Council Directive 96/23/EC. Data reported in 2005 were from the 25 EU MSs, whereas for the subsequent years (2006–2010) data have been gathered from 27 EU MSs, following the accession of Romania and Bulgaria to the EU.

Results from suspect sampling are not included, as these results are considered not to be representative of the actual occurrence of chemical residues and contaminants. As stated above, suspect sampling arises (i) as a follow-up to the occurrence of a non-compliant result and/or (ii) on suspicion of illegal treatment at any stage of the food chain and/or (iii) on suspicion of non-compliance with the withdrawal periods for authorised VMPs (Articles 5, 11 and 24 of Council Directive 96/23/EC, respectively).

A non-compliant result refers to an analytical result exceeding the permitted limits or, in the case of prohibited substances, any measured level with sufficient statistical certainty that it can be used for legal purposes.[23] As mentioned above, for VMPs, MRLs are laid down in Commission Regulation (EU) No 37/2010. For pesticides, maximum residue levels are laid down in Regulation (EC) No 396/2005. MLs for contaminants are laid down in Commission Regulation (EC) No 1881/2006. National tolerance levels are sometimes applied by individual MSs for contaminants where no EU maximum levels have been established. For some of the non-allowed veterinary medicinal products, for which no permitted limit can be set, minimum required performance limits (MRPLs) have been established (Commission Decision 2002/657/EC[24]) to make results of residue monitoring comparable between laboratories and MSs; for the residues of some of these substances that are not licensed within the EU for the use in bovine animals, such as chloramphenicol, nitrofurans and their metabolites, and medroxyprogesterone acetate, MRPLs have been established (Commission Decision 2003/181/CE[25]).

[23] As laid down in Article 6 of Decision 2002/657/EC, the result of an analysis shall be considered non-compliant if the decision limit of the confirmatory method for the analyte is exceeded. Decision limit is defined in Article 6(3) as the lowest concentration at which the method can confirm with a defined statistical certainty (99 % for substances for which no permitted limit has been established, and 95 % for all other substances) that the particular analyte is present.

[24] Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (2002/657/EC). OJ L 221, 17.8.2002, p. 8–36.

[25] Commission Decision of 13 March 2003 amending Decision 2002/657/EC as regards the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin (2003/181/EC). OJ L 71, 15.3.2003, p. 17–18.

It should be noted that information on the number of total analyses performed for an individual substance is transmitted only by those MSs that were reporting at least one non-compliant result for that substance. Therefore, it is not possible to extract from the data supplied complete information on the individual substances from each subgroup tested or on the number of samples tested for an individual substance where no non-compliant result is reported.

In addition, in some cases, the same samples were analysed for different substance groups/sub-groups and therefore the number of substance groups/subgroups tested is higher than the total number of samples collected. It should be noted that there is a lack of harmonisation regarding details provided on non-compliant samples for the NRCPs from MSs. This hampers the interpretation and the evaluation of these data. Moreover, no information is readily available on the nature of the positive samples (i.e. whether this refers to muscle, liver, kidney or skin/fat samples) and these results often give no indication of the actual measured concentrations of residues or contaminants. As a result, in the absence of substance-specific information and the actual concentration of a residue or contaminant measured, these data do not allow for an assessment of consumer exposure. In addition, particularly in the case of prohibited substances, much of the testing may be done in matrices such as urine, faeces, hair and so no data on residue levels in edible tissues are available.

In spite of the limitations highlighted above, an overall assessment of these data indicates that the percentage of non-compliant results is of a low order of magnitude as compared to the total number of samples tested.

Table 3: Non-compliant (NC) results[a] for prohibited substances (Group A) in bovine animals reported from national residue monitoring plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[b] In brackets: number of Member States providing NC data.

Substance / Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
A1 Stilbenes	0	12 743	0	10 805	0	12 539	0	13 182	0	13 093	0	13 216
	0		0		0		0		0		0	
A2 Thyreostats	42	5 552	29[c]	5 539	35	4 802	32	5 361	0	5 638	8	4 966
Ethylthiouracil	1 (1)		0		0		0		0		0	
5-Methyl-2-thiouracil	0		0		0		1 (1)		0		0	
Thiouracil	41 (2)		29 (6)		35 (3)		31 (1)		0		8 (1)	
A3 Steroids	51	30 074	108[d]	29 445	89	28 171	84	27 073	101	28 009	68	28 018
17-Alpha nortestosterone	1 (1)		0		0		0		0		0	
Betamethasone[e]	1 (1)		0		0		0		1 (1)		0	
Boldenone (boldenone -alpha)	0		53 (4)		0		3 (2)		5 (3)		1 (1)	
Boldenone (boldenone -beta)	0		0		14 (3)		21 (1)		0		1 (1)	
Boldenone	1 (1)		1 (1)		1 (1)		0		1 (1)		0	
Boldione	0		1 (1)		0		0		0		0	
Dexamethasone[e]	31 (2)		23 (2)		26 (2)		29 (2)		62 (3)		45 (1)	
Epinandrolone	14 (1)		15 (1)		5 (1)		2 (1)		1 (1)		4 (1)	
Estradiol-17- alpha	0		0		0		1 (1)		1 (1)		0	
Estradiol-17-beta	0		4 (1)		0		1 (1)		3 (1)		0	
Ethinylestradiol	0		0		1 (1)		0		0		0	
Nandrolone	0		1 (1)		4 (1)		17 (3)		4 (2)		5 (2)	
Nortestosterone cypionate	0		0		10 (1)		0		0		0	
Prednisolone[e]	2 (1)		3 (1)		8 (1)		2 (1)		2 (1)		0	
Prednisone[e]	1 (1)		1 (1)		3 (1)		0		0		0	
Progesterone	0		1 (1)		10 (1)		7 (1)		20 (1)		10[f] (1)	
Testosterone (17-beta and 1-alpha)	0		5 (3)		7 (4)		1(1)		1 (1)		2 (1)	
A4 Resorcylic acid lactones (RALs)	28	12 104	55	11 664	69	12 314	57	12 317	5	12 140	7	13 087
alpha-zearalanol (Zeranol)	14 (4)		34 (3)		39 (4)		20 (3)		3 (2)		6 (2)	
beta-zearalanol (Taleranol)	13 (3)		21 (3)		30 (4)		33 (3)		2 (2)		1 (1)	
Zearalanone	1 (1)		0		0		4 (1)		0		0	

Table 3: Continued.

Substance / Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
A5 Beta-Agonists	6	23 686	2	23 473	2	22 518	3	24 907	17	25 600	28	31 260
Cimaterol	0		0		0		1 (1)		0		0	
Clenbuterol	5 (3)		1 (1)		0		2 (2)		17 (3)		28 (3)	
Isoxsuprine	1 (1)		1 (1)		2[(g)] (1)		0		0		0	
A6 Annex IV compounds	7	15 377	8	14 493	11	12 598	12	14 547	9	15 073	11	14 023
Chloramphenicol	2 (1)		2 (2)		9 (6)		8 (5)		9 (3)		8 (5)	
Chlorpromazine	0		0		0		3 (1)		0		0	
Furazolidone/AOZ	0		0		1 (1)		0		0		3 (2)	
Furaltadone/AMOZ	1 (1)		0		0		1 (1)		0		0	
Nitrofurazone/SEM	3 (2)		5 (2)		1 (1)		0		0		0	
Metronidazole	1 (1)		0		0		0		0		0	
Dimetridazole	0		1 (1)		0		0		0		0	

[a] One sample can be non-compliant for more than one substance.
[b] Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm
[c] Several MSs claimed that the presence of thiouracil was not due to illegal treatment but was caused by feed containing cruciferous plants.
[d] Several MSs claimed that residue findings of boldenone-alpha and epinandrolone were not attributable to illegal treatment of animals. The positive findings were more likely to the endogenous production of these substances.
[e] Two MSs tested for corticosteroids under Group A3 substances; other MS tested for corticosteroids under Group B2f substances.
[f] MS claimed result was due to naturally occurring hormone. No evidence of misuse was proved after investigations.
[g] Isoxsuprine found in calves. The MS claimed that DuphaspasminR was used in cows and most likely the substance reached the calves through maternal transfer.

Table 4: Non-compliant (NC) results[a] for Veterinary Medicinal Products (Antibacterial substances and other veterinary drugs, Groups B1 and B2) in bovine animals reported from National Residue Monitoring Plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission [(b)]. In brackets: number of Member States providing NC data.

Substance / Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B1 Antibacterials	54	24 435	71	25 239	57	23 657	79	25 054	82	27 012	91	29 376
Antibacterials (un-specified)	*0*		*7 (3)*		*21 (3)*		*17 (3)*		*5 (3)*		*15 (2)*	
Aminoglycosides	*11*		*7*		*2*		*4*		*5*		*10*	
Dihydrostreptomycin	4 (2)		3 (3)		0		3 (1)		4 (3)		7 (4)	
Gentamicin	1 (1)		0		1 (1)		1 (1)		1 (1)		3 (1)	
Neomycin	6 (4)		4 (2)		1 (1)		2 (1)		1 (1)		4 (1)	
Florfenicol	*3 (1)*		*0*		*1 (1)*		*2 (1)*		*0*		*0*	
Fluoroquinilones	*1*		*4*		*5*		*1*		*4*		*2*	
Ciprofloxacin	0		1 (1)		0		1 (1)		0		0	
Danofloxacin	0		0		0		0		0		1 (1)	
Difloxacin	0		0		5 (1)		0		0		0	
Enrofloxacin	1 (1)		2 (2)		0		0		1 (1)		1 (1)	
Marbofloxacin	0		1 (1)		0		0		2 (2)		0	
Flumequin	0		0		0		0		1 (1)		0	
Macrolides	*3*		*4*		*1*		*4*		*2*		*7*	
Neospiramycin	1 (1)		0		0		1 (1)		0		0	
Spiramycin	1 (1)		0		0		1 (1)		0		2 (1)	
Tilmicosin	0		1 (1)		0		0		0		1 (1)	
Tulathromycin	0		2 (1)		0		1 (1)		0		0	
Tylosin, Tylosin A	1 (1)		1 (1)		1 (1)		1 (1)		2 (1)		4 (4)	
Penicillins	*4*		*5*		*4*		*6*		*5*		*13*	
Amoxycillin	1 (1)		4 (3)		3 (3)		1 (1)		2 (1)		3 (1)	
Ampicillin	0		0		0		0		0		3 (2)	
Benzylpenicillin	0		1 (1)		1 (1)		3 (1)		2 (1)		6 (3)	
Penicillin	3 (2)		0		0		2 (1)		1 (1)		1 (1)	
Quinolones	*0*		*0*		*0*		*4*		*0*		*0*	
Oxolinic acid	0		0		0		1 (1)		0		0	
Sarafloxacin	0		0		0		3 (1)		0		0	
Sulfonamides	*13*		*14*		*8*		*7*		*20*		*20*	
Sulfadiazine	2 (2)		3 (3)		4 (3)		2 (2)		3 (1)		6 (5)	
Sulfadimethoxine	3 (1)		5 (2)		1 (1)		4 (2)		7 (3)		1 (1)	
Sulfadimidine	2 (2)		5 (3)		2 (2)		0		2 (1)		8 (1)	

Table 4: Continued.

Substance Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
Sulfadoxine	1 (1)		0		0		0		1 (1)		1 (1)	
Sulfamethazine	0		0		0		0		3 (1)		1 (1)	
Sulfamethoxyoyridazine	0		0		0		0		4 (2)		2 (1)	
Sulfamerazine	3 (3)		0		1 (1)		0		0		1 (1)	
Sulfamonomethoxine	0		1 (1)		0		0		0		0	
Sulfaethoxypyridazine	0		0		0		1 (1)		0		0	
Sulfapyridine	1 (1)		0		0		0		0		0	
Sulfonamides	1 (1)		0		0		0		0		0	
Tetracyclines	*19*		*30*		*15*		*34*		*43*		*24*	
Chlortetracylcine	0		3 (2)		2 (1)		2 (2)		5 (4)		1 (1)	
Doxycycline	4 (1)		1 (1)		0		2 (2)		0		2 (2)	
Epi-chlortetracycline	0		0		0		0		2 (1)		0	
Epi-oxytetracycline	1 (1)		0		0		0		0		0	
Oxytetracycline	13 (4)		21 (7)		8 (3)		23 (4)		28 (8)		15 (5)	
Tetracycline	1 (1)		5 (2)		5 (2)		7 (2)		8 (4)		6 (3)	
B2a Anthelmintics	3	4 975	8	4 875	4	4 853	2	5 409	0	5 678	0	6 105
Doramectin	0		3 (2)		0		0		0		0	
Fenbendazole	0		0		1 (1)		0		0		0	
Ivermectin	3 (2)		3 (2)		2 (2)		2 (2)		0		0	
Moxidectin	0		1 (1)		0		0		0		0	
Oxfendazole	0		1 (1)		1 (1)		0		0		0	
B2b Anticoccidials	0	1 763	0	1 219	3	1 365	2	1 649	2	1 521	3	1 068
Lasalocid	0		0		3 (1)		1 (1)		1 (1)		0	
Salinomycin	0		0		0		1 (1)		1 (1)		0	
Sulfadiazine	0		0		0		0		0		3 (1)	
B2c Carbamates and pyrethroids	0	1 685	0	1 771	0	1 769	0	2 008	0	2 133	0	1 739
B2d Sedatives	0	2 319	0	2 105	0	2 183	10	2 262	0	2 713	0	2 628
Acepromazine	0		0		0		1 (1)		0		0	
Promazine	0		0		0		9 (1)		0		0	
B2e NSAIDs	14	4 735	6	4 788	7	4 816	8	5 123	6	4 754	14	4 257
Antipyrin-4-Methylamino	0		1 (1)		0		0		0		0	
Diclofen (diclofenac)	2 (2)		1 (1)		2 (2)		0		0		0	
Flufenamic-acid	0		0		1 (1)		0		0		0	
Ibuprofen	3 (1)				1 (1)		0		0		0	

Table 4: Continued.

Substance / Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
Flunixin-Meglumine	1 (1)		1 (1)		0		1 (1)		2 (1)		0	
Meloxicam	1 (1)		0		1 (1)		1 (1)		0		0	
Oxyphenbutazone anhydrate	0		0		0		1 (1)		0		0	
Phenylbutazone	5 (2)		3 (2)		1 (1)		5 (4)		2 (1)		14 (5)	
Sodium salicylate	2 (1)		0		0		0		0		0	
Tolfenamic acid	0		0		1 (1)		0		2 (1)		0	
B2f Other	21	6 324	22	5 676	19	5 677	20	6 031	11	5 467	15	6 968
Betamethasone(c)	0		0		0		0		0		1 (1)	
Dexamethasone(c)	17 (3)		10 (5)		13 (5)		12 (5)		6 (3)		11 (6)	
Methylprednisolone(c)	0		0		2 (2)		2 (2)		1 (1)		0	
Prednisolone(c)	4 (2)		9 (3)		3 (1)		6 (2)		3 (1)		3 (1)	
Prednisone(c)	0		2 (1)		0		0		0		0	
Triamcinolone acetonide(c)	0		1 (1)		1 (1)		0		1 (1)		0	

[a] One sample can be non-compliant for more than one substance.
[b] Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm.
[c] Most MSs tested for corticosteroids under Group B2f substances; two MSs tested for corticosteroids under Group 3A substances.

Table 5: Non-compliant (NC) results[a,b] for other substances and environmental contaminants (Group B3) in bovine animals reported from National Residue Monitoring Plans, 2005–2010 (targeted sampling). Information extracted from the reports published by the European Commission.[c] In brackets: number of Member States providing NC data.

Substance / Sub-group	2010 (EU27)		2009 (EU27)		2008 (EU27)		2007 (EU27)		2006 (EU27)		2005 (EU25)	
	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total	NC	Total
B3a Organochlorine compounds	2	2 960	8	2 847	12	2 719	8	2 705	2	3 021	4	3 098
Dioxins (WHO-PCDD/F-TEQ)	1 (1)		3 (2)		0		2 (1)		1 (1)		0	
Dioxins and DL-PCBs (WHO-PCDD/F-PCB-TEQ)	0		4 (3)		10 (2)		5 (2)		0		0	
PCBs sum	0		0		1 (1)		0		0		2 (2)	
gamma-HCH (HCH, Lindane)	1 (1)		1 (1)		0		1 (1)		0		0	
HCH-Beta	0		0		1 (1)		0		0		2 (1)	
Pentachlorophenol	0		0		0		0		1 (1)		0	
B3b Organophosphorous compounds	0	1 500	0	1 711	2	1 477	0	1 865	0	2 188	0	2 085
DDVP (Dichlorvos)	0		0		1 (1)		0		0		0	
Fenitrothion	0		0		1 (1)		0		0		0	
B3c Chemical elements	104	3 038	50	2 832	52	3 054	64	3 198	63	3 454	106	3 222
Cadmium	56 (7)		34 (10)		38 (8)		55 (11)		52 (12)		89 (15)	
Chromium	0		0		0		0		0		5 (1)	
Copper	28 (1)		0		0		0		0		0	
Lead	3 (2)		1 (1)		2 (1)		8 (5)		7 (3)		12 (5)	
Mercury	17 (1)		15 (1)		12 (1)		1 (1)		4 (1)		0	
B3d Mycotoxins	3	1 097	0	1 106	4	1 191	6	1 437	2	1 569	0	1 116
Aflatoxin B1	0		0		1 (1)		2 (1)		2 (1)		0	
Ochratoxin A	0		0		0		4 (1)		0		0	
Zearalenone (mycotoxin F)	3 (1)		0		3 (1)		0		0		0	
B3e Dyes	0	0	0	0	0	0	0	0	0	0	0	0
B3f Other	0	534	0	1 094	0	686	0	482	0	569	0	553

[a] One sample can be non-compliant for more than one substance.
[b] National tolerance levels are applied by individual MSs for contaminants where no EU maximum levels have been established.
[c] Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm.

A summary of the data presented in the previous tables (Tables 3, 4 and 5) shows that 1 990 of the 808 697 (0.25 %) samples analysed in the EU NRCPs during the period 2005–2010 were non-compliant for one or more substances listed in Annex I of Directive 96/23/EC. Further details are presented in Table 6. As mentioned above, one sample can be non-compliant for multiple substances, so that the number of non-compliant results is higher than the number of non-compliant samples. For example, for B3 substances, there were 498 non-compliant results in 473 non-compliant samples.

Table 6: Analysis of non-compliant (NC) samples[a] as reported in the NRCPs[b] for the period 2005–2010 in the EU.

Period 2005–2010	Group A	Group B1-B2	Group B3	Total
Total samples analysed[c]	476 550	282 557	49 590	808 697
Farm level	230 884	33 591	4 376	268 851
Slaughterhouse level	245 666	248 966	45 214	539 846
Total NC samples	899	618	473	1 990
Farm level	403	55	16	474
Slaughterhouse level	496	563	457	1 516

[a] One sample can be non-compliant for more than one substance.
[b] Published at http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm.
[c] Some of the samples were analysed for several substances in different subgroups (e.g. same sample analysed for B3a, B3b and B3c), this total represents the total number of samples analysed for at least one substance in the group.

It should be noted that the data in Tables 3–5 provide the results for sampling and testing carried out by MS under the terms of Council Directive 96/23/EC within the NRCPs. However, there may be other chemical substances of relevance for control in bovine animals, particularly in the case of contaminants which are not included in the NRCPs at all or which are not systematically covered by the NRCPs. Some of these substances are addressed further under TOR 3 of this opinion ('New hazards').

2.3.2. Analysis of the data

Of the total number of samples taken for analysis during the period 2005–2010, 33.2 % were taken at farm level while the remaining 66.8 % were taken at slaughterhouse level. It should be noted that sample details are not always available. Results indicate that:

- 0.25 % of the total samples were non-compliant for one or more substances, with 0.19 %, 0.22 % and 0.95 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively;
- 0.18 % of all samples taken at farm level were non-compliant for one or more substances, with 0.17 %, 0.16 % and 0.37 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively;
- 0.28 % of all samples taken at slaughterhouse level were non-compliant for one or more substances, with 0.20 %, 0.23 % and 1.01 % being non-compliant for Group A, Group B1/B2 and Group B3 substances, respectively.

The highest overall proportion of non-compliant samples (0.95 %) was for Group B3 substances, contaminants, representing largely exceedances of the MLs/MRLs specified for these substances. For Group A, prohibited substances (0.19 %), and for Group B1/B2 substances, VMPs (0.22 %), the proportions of non-compliant samples were similar, representing largely illicit use of prohibited substances and exceedances of the MRLs specified for VMPs, respectively.

An analysis of the results for sampling at farm level compared with slaughterhouse level indicates that, for prohibited substances (Group A), the rate of non-compliant results determined for sampling at farm

level is slightly lower but broadly similar to that for sampling at slaughterhouse level. The majority (94 %) of samples found to be non-compliant for prohibited substances relate to those having anabolic effects (thyreostats, steroids, zeranol, beta-agonists), and only a minority (6 %) were non-compliant for substances such as chloramphenicol, nitrofurans and nitroimidazoles. Farm-level sampling is an integral component of the system for controlling illicit use of prohibited substances in food-producing animals, particularly in the case of substances having anabolic effects.

One issue of controversy has been the extent of usage of growth-promoting substances in beef and veal production in the EU. It has been suggested, based on the findings of anabolic substances in illicit supply chains and on farms by veterinary inspection/police, that there may be a relatively widespread abuse of anabolic agents in some beef/veal production. It has been suggested, also, that one of the reasons why this abuse of anabolic agents may not be identified in the NRCP testing is that cocktails of different substances, each one at a low level, may be used resulting shortly after their administration in residue levels in tissues and/or biological fluids below the detection capability of analytical methods (Vincenti et al., 2009; Pezzolato et al., 2011). In addition, a still active black-market trade may provide dishonest farmers with prohibited substances including new compounds referred to as designers drugs (e.g. norbolethone, tetrahydrogestrinone and desoxy-methyltestosterone) which are not included in the list of the substances subjected to chemical monitoring under the NRCPs (WTO, 2008; De Brabander et al., 2009). Finally, despite the known limitations of histological screening (Mooney et al., 2009), a pilot study (Nebbia et al., 2011) involving 295 veal calves and 1 035 finishing bulls revealed the occurrence of lesions that could be ascribed to the exposure to beta-agonists, corticosteroids or sex steroids in 11.7, 17.7, and 31.9 % of the examined cases, respectively. Even if unspecific lesions could be present in half of the cases, the percentage of 'suspect' animals was found to be several orders of magnitude higher than the official figures, in line with suggestions estimating that the real non compliant results for the category of sex steroids alone as being between 5 and 15 % in bovine animals (Stephany, 2010). While the results from NRCP testing do not allow for a final conclusion to be drawn on this topic, the need for new approaches based on biological determinants that may complement the analytical techniques has been proposed (Vascellari et al., 2008; Mooney et al., 2009; Riedmaier et al., 2009).

An analysis of the results for sampling at farm level compared to slaughterhouse level indicates that for VMPs (Group B1/B2) there is little difference in the rate of non-compliant results determined. However, sampling at slaughterhouse level may be more appropriate for identifying non-compliant results for VMPs, based on compliance with or exceedance of the specified MRLs in edible tissue.

In the case of contaminants (Group B3), the rate of non-compliant samples determined for sampling at slaughterhouse level is markedly higher than for sampling at farm level. Indeed, sampling for Group B3 substances is more appropriate, generally, at slaughterhouse level ,where identification of non-compliant results, based on compliance with or exceedance of specified MRLs/MLs in edible tissues, can be made.

It should also be noted that a direct comparison of data from the NRCPs over the years is not entirely appropriate as the test methods used and the number of samples tested for an individual residue varied between MSs, and the specified MRLs/MLs for some substances may change over time. In addition, there are ongoing improvements in analytical methods, in terms of method sensitivity, accuracy and scope (i.e. number of substances covered by the method), which affect inter-year and inter-country comparisons. Therefore, the cumulative data from the NRCPs provide only a broad indication of the prevalence and nature of non-compliant samples.

In conclusion, this compilation of data clearly indicates the low prevalence of abiotic hazards (residues and contaminants) in bovine animals. Only 0.25 % of the total number of analysed samples were non-compliant for one or more substances listed in Annex I of Directive 96/23/EC. Potentially higher exposure of consumers to these substances from bovines takes place only incidentally, as a result of mistakes and/or non-compliance with known and regulated procedures.

2.3.3. Criteria for the evaluation of the likelihood of the occurrence of residues or contaminants in bovine animals

Independent from the occurrence data as reported from the NRCPs, substances or groups of chemical substances that may enter the food chain were also evaluated for the likelihood that potentially toxic or undesirable substances might occur in bovines, including consideration of the various types of bovine animals used for meat production.

For prohibited substances and VMPs/feed additives, the following criteria were used:

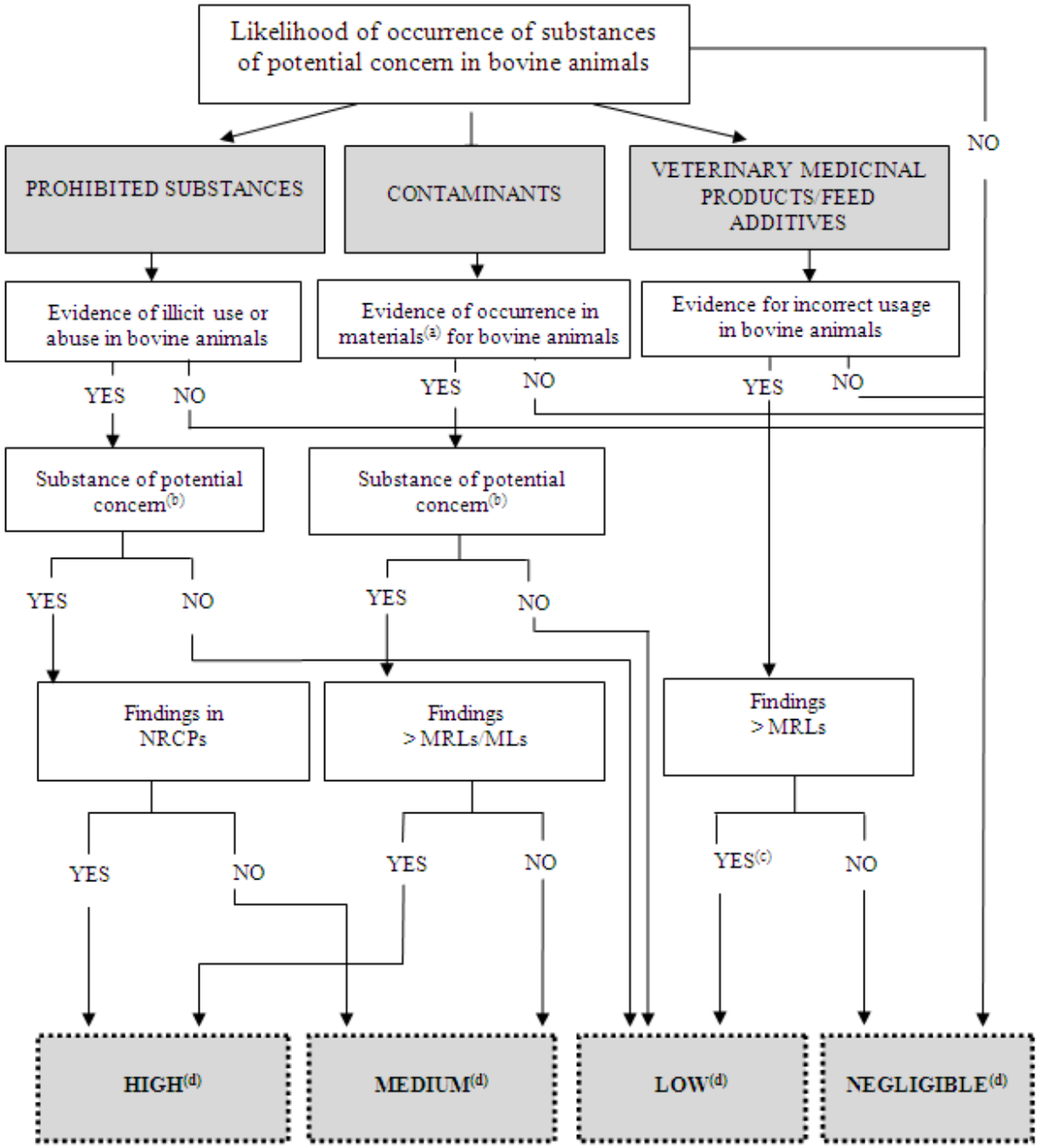
- the likelihood of the substance(s) being used in an illicit or non-compliant way in bovine animals (suitability for bovine production; commercial advantages);
- the potential availability of the substance(s) for illicit or non-compliant usage in bovine animal production (allowed usage in Third Countries; availability in suitable form for use in bovine animals; non-authorised supply chain availability ('black market'); common or rare usage as a commercial licensed product);
- the likelihood of the substance(s) occurring as residue(s) in edible tissues of bovine animals based on the kinetic data (pharmacokinetic and withdrawal period data; persistence characteristics; special residue issues, e.g. bound residues of nitrofurans);
- toxicological profile and nature of hazard and the relative contribution of residues in bovine animals and meat to dietary human exposure.

For contaminants, the following criteria were considered:

- the prevalence (where available) of occurrence of the substances in animal feeds/forages and pastures, and in the specific environmental conditions of the farms;
- the level and duration of exposure, tissue distribution and deposition including accumulation in edible tissues of bovine animals;
- toxicological profile and nature of hazard, and the relative contribution of residues in bovine animals and meat to dietary human exposure.

2.3.4. General flow chart

Considering the above mentioned criteria, a flow-chart approach was used for ranking of the chemical residues and contaminants of potential concern. The outcome of the NRCPs (indicating the number of non-compliant results), the evaluation of the likelihood that residues of substances of potential concern can occur in bovine animals and the toxicological profile of the substances were considered in the development of the general flow-chart, presented in Figure 1.



ML, maximum level: MRL, maximum residue limits; NRCP, national residue control plan.
[a] Contaminants from the soil and the environment, associated with feed material, are considered to be part of the total feed intake for the purposes of this opinion.
[b] Potential concern was based on the toxicological profile and nature of hazard for the substances.
[c] The CONTAM Panel notes that the ranking of VMPs/feed additives was carried out in the general context of authorised usage of these substances in terms of doses, route of treatment, animal species and withdrawal periods. Therefore, this ranking is made within the framework of the current regulations and control and within the context of a low rate of exceedances in the NRCPs.
[d] See definitions provided in Section 2.3.5, below.

Figure 1: General flow-chart used for the ranking of residues and contaminants of potential concern that can be detected in bovine animals.

2.3.5. Outcome of the ranking of residues and contaminants of potential concern that can occur in bovine carcasses.

Four categories were established resulting from the application of the general flow-chart:

Category 1—negligible potential concern

Substance irrelevant in bovine production (no known use at any stage of production); no evidence for illicit use or abuse in bovine animals; not or very seldom associated with exceedances in MRLs in control plans; no evidence of occurrence as a contaminant in bovine feeds.

Category 2—low potential concern

VMPs/feed additives which have an application in bovine animal production; residues above MRLs are found in control plans, but substances are of low toxicological concern[41]; contaminants and prohibited substances with a toxicological profile that does not include specific hazards following accidental exposure of consumers, and which are generally not found or are not found above MLs in bovine animals.

Category 3—medium potential concern

Contaminants and prohibited substances to which bovine animals are known to be exposed and/or with a history of misuse, with a toxicological profile that does not entirely exclude specific hazards following accidental exposure of consumers; evidence for residues of prohibited substances being found in bovine animals; contaminants generally not found in concentrations above the MRLs/MLs in edible tissues of bovine animals.

Category 4—high potential concern

Contaminants and prohibited substances to which bovine animals are known to be exposed and with a history of misuse, with a distinct toxicological profile comprising a potential concern to consumers; evidence for ongoing occurrence of residues of prohibited substances in bovine animals; evidence for ongoing occurrence and exposure of bovine animals to feed contaminants.

2.3.5.1. Substances classified in the high potential concern category

2.3.5.1.1. Contaminants: dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs)

In the high potential concern category are dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) as the occurrence data from monitoring programmes show a number of incidents due to contamination of feed, such as illegal disposal of dioxin and DL-PCB containing waste materials into feed components, or open drying of feed components with dioxin-containing fuel materials.

(a) Dioxins[42]

Dioxins are persistent organochlorine contaminants that are not produced intentionally, have no targeted use, but are formed as unwanted and often unavoidable by-products in a number of thermal and industrial processes. Because of their low water solubility and high lipophilic properties, they bioaccumulate in the food chain and are stored in fatty tissues of animals and humans. The major

[41] The CONTAM Panel notes that the ranking of VMPs/feed additives was carried out in the general context of authorised usage of these substances in terms of doses, route of treatment, animal species and withdrawal periods. Therefore, this ranking is made within the framework of the current regulations and control and within the context of a low rate of exceedances in the NRCPs.

[42] The term 'dioxins' used in this opinion refers to the sum of polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs).

pathway of human dioxin exposure is via consumption of food of animal origin which generally contributes more than 80 % of the total daily dioxin intake (EFSA, 2010a). A number of incidents in the past 15 years were caused by contamination of feed with dioxins. Examples are feeding of contaminated citrus pulp pellets, kaolinitic clay containing potato peels or mixing of compound feed with contaminated fatty acids.

All these incidents were caused by grossly negligent or criminal actions and led to widespread contamination of feed and subsequently to elevated dioxin levels in the animals and the foodstuffs produced from them. Besides these incidents, extensive production of bovine animals may lead also to elevated dioxin levels, especially in areas with substantial environmental contamination. In this respect, calves are of importance as, owing to their low body fat content, the lipophilic dioxins may reach considerable concentrations in the fat fraction (the basis for the MLs).

Dioxins have a long half-life and are accumulated in various tissues. The findings of elevated levels in food are of public health concern due to potential for effects on liver, thyroid, immune function, reproduction and neuro-development (EFSA, 2005a, 2010a). The available data indicate that a substantial part of the European population is in the range of or already exceeding the tolerable weekly intake (TWI) for dioxins and DL-PCBs. A report on 'Monitoring of Dioxins and PCBs in Food and Feed' (EFSA, 2012b) estimated that between 1.0 and 52.9 % of individuals were exposed above the TWI of 14 pg TEQ/kg body weight (b.w.) for the sum of dioxins and DL-PCBs. In addition to milk and dairy products and fish and seafood, meat and meat products also contributed significantly to total exposure. Dioxin concentrations in 571 meat and fat samples from bovines were reported by several MS to EFSA following a call for data. Levels ranged from 0.04 to 8.75 (mean: 0.53, median: 0.38) pg WHO-TEQ_{2005}/g fat. (EFSA, 2012b). Due to the high toxic potential of dioxins and the incidence of samples of bovine meat exceeding the maximum limit, efforts need to be undertaken to reduce exposure where possible.

In summary, based on the high toxicity and the low maximum levels set for meat and fat of bovine animals (see Table 1), and considering that food of animal origin contributes significantly (> 80 %) to human exposure, dioxins have been ranked in the category of substances of high potential concern.

(b) Dioxin-like polychlorinated biphenyls (DL-PCBs)

In contrast to dioxins, PCBs had widespread use in numerous industrial applications, generally in the form of complex technical mixtures. Due to their physico-chemical properties, such as non-flammability, chemical stability, high boiling point, low heat conductivity and high dielectric constants, PCBs were widely used in industrial and commercial closed and open applications. They were produced for over four decades, from 1929 onwards until they were banned, with an estimated total world production of 1.2–1.5 million tonnes. According to Council Directive 96/59/EC[43], MS were required to take the necessary measures to ensure that used PCBs are disposed of and equipment containing PCBs are decontaminated or disposed of at the latest by the end of 2010. Earlier experience has shown that illegal practices of PCB disposal may occur resulting in considerable contamination of animals and foodstuffs of animal origin.

Based on structural characteristics and toxicological effects, PCBs can be divided into two groups. One group consists of 12 congeners that can easily adopt a coplanar structure and have the ability to bind to the Ah-receptor, thus showing toxicological properties similar to dioxins (effects on liver, thyroid, immune function, reproduction and neuro- development). This group of PCBs is therefore called 'dioxin-like PCBs' (DL-PCBs). The other PCBs do not show dioxin-like toxicity but have a different toxicological profile, in particular with respect to effects on the developing nervous system

[43] Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT). OJ L 243, 24.9.1996, p. 31–35.

and neurotransmitter function. This group of PCBs is called 'non dioxin-like PCBs' (NDL-PCBs) (see below).

As for dioxins, extensive production of bovine animals may also lead to elevated levels of DL-PCBs in bovine animal tissues. For example, a study conducted in Switzerland in 2006 indicated that veal from extensive production (suckler cows) on average contained higher levels of DL-PCBs than samples taken from animals raised in intensive indoor production (feeding with milk replacers). A substantial fraction of the veal samples from extensive production exceeded the MLs for the sum of dioxins and DL-PCBs (BAG, 2008). Exceedances of the action levels for DL-PCBs in bovine animals were also found frequently in Southern Germany[44,45]. DL-PCB concentrations in 571 meat and fat samples from bovines were reported by several MS to EFSA following a call for data. Levels ranged from 0.01 to 22.41 (mean: 1.09, median: 0.60) pg WHO-TEQ_{2005}/g fat (EFSA, 2012b).

As DL-PCBs, in general, show a comparable lipophilicity, bioaccumulation, toxicity and mode of action as dioxins (EFSA, 2005a), these two groups of environmental contaminants are regulated together in European legislation and are considered together in risk assessments. Based on the high toxicity, widespread use and potential for improper disposal practices of technical PCB mixtures, DL-PCBs have been ranked in the category of substances of high potential concern.

2.3.5.2. Substances classified in the medium potential concern category

2.3.5.2.1. Prohibited substances: stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones, beta-agonists, chloramphenicol and nitrofurans

(a) Stilbenes

The toxicity of stilbenes is well-established (for review see Waltner-Toews and McEwen, 1994) and this has led to their prohibition for use as growth promoters in animals in most countries, also based on their involvement in the baby food scandal in the late 1970's (Loizzo et al., 1984). In particular, diethylstilbestrol is a proven human genotoxic carcinogen (group I IARC) (IARC, 2012), while sufficient evidence for hexestrol and limited evidence for dienestrol for carcinogenicity in animals were found (IARC, 1979). Diethylstilbestrol is associated with cancer of the breast in women who were exposed while pregnant; and also causes adenocarcinoma in the vagina and cervix of women who were exposed *in utero*; finally, a positive association has been observed between exposure to diethylstilbestrol and cancer of the endometrium, and between *in-utero* exposure to diethylstilbestrol and squamous cell carcinoma of the cervix, and cancer of the testis. In treated bovines, residues of the active unchanged compound may be found especially in liver even after a long time (26 days) from the withdrawal of treatment (Hoffmann and Evers, 1986). In 1981, the use of stilbenes in all species of food-producing animals was prohibited in the European Community by Directive 81/602/EEC[46].

Diethylstilbestrol, and other stilbenes such as hexestrol and dienestrol, are likely to be available on the black-market and, therefore, might be available for illicit use in cattle production. No non-compliant results for stilbenes in bovine samples have been reported from the European NRCPs 2005–2010, indicating that abuse of stilbenes in cattle production in the EU is unlikely.

Considering that stilbenes have proven toxicity for humans and are effective for growth promotion in cattle, these substances are ranked as of medium potential concern. However, considering that there is no evidence for current use of stilbenes in bovine production and that no non-compliant results have been found over a number of years of NRCP testing, control measures for stilbenes might be focused on identifying any potential future abuse of these substances in bovine production in the EU.

[44] http://www.lgl.bayern.de/lebensmittel/warengruppen/wc_06_fleisch/ue_2010_weidetiere.htm
[45] http://www.untersuchungsaemter-bw.de/pdf/oekomonitoring2009.pdf
[46] Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action. OJ L 222, 7.8.1981, p. 32–33.

(b) Thyreostats

Thyreostats are a group of substances that inhibit the thyroid function, resulting in decreased production of the thyroid hormones triiodothyronine (T3) and thyroxine (T4). Enlargement of the thyroid gland has been proposed as a criterion to identify illicit use of these compounds (Vos et al., 1982; Vanden Bussche et al., 2009). They are used in human and in non-food-producing animal medicine to deal with hyperthyroidism. The use of thyreostats for animal fattening is based on weight gain caused by filling of the gastro-intestinal tract and retention of water in muscle tissues (Courtheyn et al., 2002). Synthetic thyreostats include thiouracil, methylthiouracil, propylthiouracil, methimazole, tapazol (methylmercaptoimidazole) and mercaptobenzimidazole (MBI). The use of synthetic thyreostats in food-producing animals has been prohibited in the European Union since 1981 (Council Directive 81/602/EC).

Naturally-occurring thyreostats include thiocyanates and oxazolidine-2-thiones, which are present as glucosinolates in plant material such as in the seeds of *Cruciferae*, like rapeseed (EFSA, 2008b; Vanden Bussche et al., 2009). Evidence for the occurrence of thiouracil in urine of cattle fed on a cruciferous-based diet has been demonstrated (Pinel et al., 2006).

Thyreostats are available on the black-market so there is the possibility for illicit use in cattle production. The results from the European NRCPs 2005–2010 show a relatively high incidence of bovine samples non-compliant for thyreostats (111 non-compliant results out of the 31 858 samples analysed for thyreostats). However, it has been shown that the source of the, generally, low levels of thiouracil determined in urine samples (< 10 µg/L) may be from exposure of cattle through their diet (Le Bizec et al., 2011). Some MS reporting the highest numbers of non-compliant samples for thiouracil state that '*the presence of thiouracil in low concentrations may be due to the animals eating cruciferous plant materia*l' and '*in line with scientific evidence, the competent authority has concluded that the residues resulted from dietary factors*'.

Thyreostats have been considered to be carcinogenic and teratogenic. While the *in utero* exposure to methimazole or propylthiouracil has been associated with aplasia cutis and a number of other congenital defects (Löllgen et al., 2011; Rodriguez-Garcia et al., 2011), an evaluation by the International Agency for Research on Cancer (IARC) evaluation found inadequate evidence in humans, but limited evidence (in the case of methimazole) and sufficient evidence (in the case of thiouracil, methylthiouracil and propylthiouracil) in experimental animals for carcinogenicity (IARC, 2001; EFSA 2008b).

Thyreostats are prohibited substances due to their potential toxicity to humans and their efficacy as growth promoters in cattle, but considering that the non-compliant results that have been found in most years of NRCP testing have been attributed largely to a dietary source, these substances are ranked as of medium potential concern. Control measures for thyreostats might focus on identifying potential abuse of these substances in bovine production in the EU.

(c) Gonadal (sex) steroids

A broad range of steroids derived from oestrogens, androgens and progestagens are available and have been used as growth-promoting agents in food-producing animals. There is an extensive body of animal production research demonstrating the efficacy of anabolic steroids, often in combination treatments of an oestrogen and an androgen (or progestagen), as growth promoters. Gonadal (sex) steroids are given to animals typically as injections or implants, but may also be administered via the skin as 'pour-on' applications (Schilt et al., 1998). All use of steroids as growth-promoting agents in food-producing animals is banned according to Council Directive 96/22/EC, as amended by Directives

2003/74/EC[47] and 2008/97/EC[48]. The latter included 17β-oestradiol in the list of prohibited substances due to its demonstrated tumour promoting (epigenetic) and tumour initiating (genotoxic) properties (Russo et al., 2003). Certain uses of 17β-oestradiol, progesterone, and norgestomet in bovine animals are allowed for therapeutic or zootechnical purposes only under veterinary control (Commission Regulation (EU) No 37/2010).

There is ample evidence that anabolic steroids influence the growth rate and feed conversion efficiency in cattle, with animals responding by increased growth rate and feed conversion efficiency (Meyer, 2001). Anabolic steroids are widely available on the black-market so there is the possibility for illicit use in cattle production. The results from the NRCPs 2005–2010 show bovine samples non-compliant for anabolic steroids. Because of the potential occurrence of some of these substances endogenously, particularly substances such as alpha-boldenone, epinandrolone (especially in pregnant cows) and the natural hormones (for a review, see Scarth et al., 2009), it is difficult to establish an accurate estimate for the level of abuse of anabolic steroids in European cattle production from these data. There are divergent views on the potential adverse effects for the consumer from residues of anabolic steroids in edible tissues of treated animals. There is concern regarding the carcinogenic effects of oestrogenic substances, and the long-term effects of exposure of prepubescent children to oestrogenic substances. In 1999 the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) performed an assessment of the potential risks to human health from hormone residues in bovine meat and meat products (SCVPH, 1999, 2000, 2002), particularly as regards the three natural hormones (17β-oestradiol, testosterone, progesterone) and the three synthetic analogues (zeranol, trenbolone acetate, melengestrol acetate) that may be legally used as growth-promoters in Third Countries. It was concluded that, taking into account both the hormonal and non-hormonal toxicological effects, the issues of concern include neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity and carcinogenicity. In consideration of concerns relating to the lack of understanding of critical developmental periods in human life as well as uncertainties in the estimates of endogenous hormone production rates and metabolic clearance capacity, particularly in prepubertal children, no threshold level and therefore no ADI could be established for any of the six hormones. According to IARC, 17β-oestradiol and steroidal oestrogens are classified as proven human carcinogens (Group 1), androgenic (anabolic) steroids as probably carcinogenic to humans (Group 2A); for most progestagens, evidence for human carcinogenicity is inadequate while that for animals varies from sufficient to inadequate (IARC, 2012).

Notwithstanding the toxicological profile of gonadal (sex) steroids, due to the low prevalence of non-compliant samples from confirmed illicit use in the NRCPs, these substances are ranked as of medium potential concern.

(d) Resorcylic acid lactones (RALs)

In the EU, zeranol was evaluated together with other hormonal growth promoters by the SCVPH (SCVPH, 1999, 2000, 2002). In these opinions it was concluded that, taking into account both hormonal and non-hormonal toxicological effects, no threshold level and therefore no ADI could be established for any of the six hormones, including zeranol. Use of zeranol as a growth promoter in cattle production was widespread in some MSs prior to its prohibition in Europe in 1985. Zeranol is widely available as a commercial product and is used extensively in Third Countries. Hence it is readily available on the market and so there is the possibility for its illicit use in cattle production in the EU. Zeranol is derived from, and can also occur as, a metabolite of the mycotoxin zearalenone, produced by *Fusarium* spp.

[47] Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. OJ L 262, 14.10.2003, p. 17–21.

[48] Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. OJ L 318, 28.11.2008, p. 9–11.

The results from the European NRCPs 2005–2010 show a relatively high incidence of bovine samples non-compliant for zeranol; 221 non-compliant results out of the 73 626 samples tested for RALs. However, it has been shown that the source of the, generally, low levels of zeranol and its metabolites determined in these samples may originate from exposure of cattle to the mycotoxin zearalenone in their diet (EFSA, 2004a). Some MS reporting the highest numbers of non-compliant samples for zeranol and its metabolites state that '*contents of alpha and beta zearalenol and of zearalenone indicate that mycotoxins are a likely cause of the findings*', '*on farm investigations were carried out for 3 samples and no evidence of abuse was found; research has shown that residues of zeranol can occur where an animal ingests contaminated feed' and 'the presence of these substances is likely due to feeding of the animals with forage contaminated with mycotoxins'*.

RALs are prohibited substances due to their potential toxicity to humans and their efficacy as growth promoters in cattle, but considering that the non-compliant results that have been found in most years of NRCP testing have been attributed largely to a dietary source, these substances are ranked as of medium potential concern. Control measures for RALs might focus on identifying potential abuse of these substances in bovine production in the EU.

(e) Beta-agonists

Beta-agonists, or β-adrenergic agonists, have therapeutic uses as bronchodilatory and tocolytic agents. A wide range of beta-agonists have been developed, such as clenbuterol, salbutamol, cimaterol, terbutaline, ractopamine, etc., and all of these are prohibited for use as growth-promoting agents in food-producing animals in the EU. Salbutamol and terbutaline are licensed human medicines indicated for the treatment of asthma and bronchospasm conditions and for prevention of premature labour, respectively. One of the beta-agonists, clenbuterol, is licensed for therapeutic use in cattle (as a tocolytic agent) and for the treatment of obstructive airway conditions in horses (Commission Regulation (EU) No 37/2010). Other beta-agonists, such as ractopamine and zilpaterol, have been approved for use in food-producing animals, including cattle, in a number of Third Countries.

The response of cattle to treatment with beta-agonists, particularly clenbuterol and salbutamol, has been widely documented. Typically, beta-agonist treatment results in increased muscle growth and increased carcass leanness. The very high doses required to achieve these effects significantly compromise animal health and well-being. The commercial benefits of using beta-agonists in cattle production, combined with the availability of these substances, indicates that illicit use of beta-agonists as growth promoters for cattle cannot be excluded. There have been a number of incidents of human toxicity linked to consumption of tissues from treated animals (liver and meat) in both European and non-European countries (Sporano et al., 1998; Shiu and Chong, 2001; Garcia-Lopez, 2002; Barbosa et al., 2005). Transient adverse effects sometimes requiring hospitalization have been reported in persons from four MSs in the 1990–2000s after eating veal and calves' liver. Toxic effects associated with the ingestion of beta-agonists residues include headache, dizziness, tremors, palpitations, tachycardia, superventricular extrasystoles, atrial fibrillation accompanied by hyperglycemia and hypokalemia (Sporano et al., 1998; Brambilla et al., 2000, Barbosa et al., 2005).

The results of the European NRCPs 2005–2010 show incidence of non-compliant results for most years, particularly involving clenbuterol. The major concern about beta-agonists seems to be related to the presence of residues of clenbuterol in calf livers due to its longer half-life in this animal category compared to other animals (Meyer and Rinke, 1991; Biolatti et al., 1994); this is consistent with the low rate of hepatic drug metabolism reported in veal calves, which appears to be further depressed in clenbuterol treated calves (Cantiello et al., 2008).

Beta-agonists, particularly clenbuterol, have known adverse biological effects in humans and are effective as repartitioning agents in young cattle but considering that lower numbers of non-compliant results have been found in recent years of the NRCP testing, these substances currently are ranked as of medium potential concern.

(f) Chloramphenicol

Chloramphenicol is an antibiotic substance, first used for the treatment of typhoid in the late 1940s. Chloramphenicol may produce idiosyncratic blood dyscrasias in humans, particularly bone marrow aplasia, or aplastic anaemia, which may be fatal. There is no clear correlation between dose and the development of aplastic anaemia and the mechanism of induction of aplastic anaemia is not fully understood (Watson, 2004). Although the incidence of aplastic anaemia associated with exposure to chloramphenicol is apparently very low, no threshold level for the induction of this idiosyncratic aplastic anaemia could be defined (EMEA, 2009). In addition, several studies suggest that chloramphenicol and some of its metabolites are genotoxic (FAO/WHO, 1988, 2004; EMEA, 2009). Considering the available evidence from *in vitro* experiments and from animal studies as well as from a case control study conducted in China, in which there was evidence for the induction of leukaemia in patients receiving a long-term treatment with Chloramphenicol, the International Agency for Research on Cancer (IARC) classified chloramphenicol as group 2A (probably carcinogenic to humans) substance (IARC, 1990). Based on these evaluations, the use chloramphenicol in food-producing animals is prohibited within the EU to avoid the exposure of consumers to potential residues in animal tissues, milk and eggs. Subsequently, chloramphenicol is included in Table 2 of Commission Regulation (EU) No 37/2010 (previously Annex IV of Council Regulation (EEC) No 2377/90).

Until its prohibition, chloramphenicol was used on food-producing animals, including cattle, for treatment of *Salmonella* infections and for prevention of secondary bacterial infections. Currently, chloramphenicol, which is licensed for use as a broad-spectrum bacteriostatic antibacterial in pets and non food-producing animals in the EU, is used also in some Third Countries for food-producing animals. Hence, chloramphenicol may be available on the black market for illicit use in cattle production. However, the availability for use on food-producing animals of related substances with similar antibacterial properties, thiamphenicol and florfenicol (with no toxicological concern), should mitigate against the illicit use of chloramphenicol in cattle production as these alternative drugs are available as prescription medicines. Non-compliant results for chloramphenicol in cattle have been reported in each year's results from the European NRCPs 2005–2010, indicating that abuse of chloramphenicol in cattle production in Europe is a continuing occurrence, although the number of non-compliant results has decreased in recent years.

Chloramphenicol has proven toxicity for humans and is effective as an antibacterial treatment for cattle but, considering that lower numbers of non-compliant results have been found in recent years of the NRCP testing, chloramphenicol currently is ranked as of medium potential concern.

(g) Nitrofurans

Nitrofurans, including furazolidone, furaltadone, nitrofurantoin and nitrofurazone, are very effective antimicrobial agents that, prior to their prohibition for use on food-producing animals in the European Union in 1995, were widely used in livestock (cattle, pigs, and poultry), aquaculture and bees. Various nitrofuran antimicrobials are still applied in human medicine particularly for the treatment of urinary tract infections. A characteristic of nitrofurans is a short half-life of the parent compounds and the formation of covalently-bound metabolites which, under the acidic conditions of the human stomach, may be released as active agents (Hoogenboom et al., 1992). These covalently-bound metabolites are used as marker residues for detecting the illicit use of nitrofurans in animal production. It should be noted that the metabolite semicarbazide (SEM) has been shown not to be an unambiguous marker for abuse of the nitrofuran drug nitrofurazone because the semicarbazide molecule may occur from other sources (Hoenicke, et al., 2004; Sarnsonova, et al., 2008; Bendall, 2009).

Nitrofurans are effective in treatment of bacterial and protozoal infections, including coccidiosis, in food-producing animals. Although prohibited for use on food-producing animals in many countries, nitrofurans are likely to be available on the black-market for illicit use in cattle production. Non-compliant results for nitrofurans in cattle have been reported in most years' results from the European

NRCPs 2005–2010, indicating that abuse of nitrofurans in cattle production in Europe is a continuing occurrence. A metabolite of furazolidone that can be released from covalently bound residues in tissues has been shown to be mutagenic and may be involved in the carcinogenic properties of the parent compound (EMEA, 1997a).

Nitrofurans have proven toxicity for humans and are effective as antibacterials for cattle but, considering that non-compliant results, other than for the non-specific marker residue SEM, are found only sporadically in the NRCP testing, these substances currently are ranked as of medium potential concern.

2.3.5.2.2. Contaminants: non dioxin-like PCBs (NDL-PCBs), chemical elements and mycotoxins

(a) Non dioxin-like PCBs (NDL-PCBs)

The non dioxin-like PCBs (NDL-PCBs) show a different toxicological profile to the DL-PCBs. In 2005, the CONTAM Panel performed a risk assessment on NDL-PCBs in food (EFSA, 2005a). In the final conclusion, the CONTAM Panel stated that no health-based guidance value for humans can be established for NDL-PCBs because simultaneous exposure to dioxin-like compounds hampers the interpretation of the results of the toxicological and epidemiological studies, and the database on effects of individual NDL-PCB congeners is rather limited. There are, however, indications that subtle developmental effects, caused by NDL-PCBs, DL-PCBs, or polychlorinated dibenzo-*p*-dioxins/polychlorinated dibenzofurans alone, or in combination, may occur at maternal body burdens that are only slightly higher than those expected from the average daily intake in European countries. In its risk assessment the CONTAM Panel decided to use the sum of the six PCB congeners -28, -52, -101, -138, -153 and -180 as the basis for their evaluation, because these congeners are appropriate indicators for different PCB patterns in various sample matrices and are most suitable for a potential concern assessment of NDL-PCBs on the basis of the available data. Moreover, the Panel noted that the sum of these six indicator PCBs represents about 50 % of total NDL-PCBs in food (EFSA, 2005a). Harmonized European maximum levels for NDL-PCBs in different food categories including meat, meat products and liver of bovine animals apply from 1 January 2012.

Levels for the sum of the above six NDL-PCBs in 271 meat and 389 fat samples from bovines were reported by several MSs to EFSA following a call for data. Levels in meat samples ranged from 0.06 to 119.3 (mean 11.0, median 6.52) µg/kg fat. Levels in the fat samples ranged from 0.00 to 273.2 (mean 3.65, median 1.34) µg/kg fat. For two kidney samples, concentrations of 0.61 and 1.12 µg/kg fat for the sum of the six NDL-PCBs were reported (EFSA, 2012b).

Because of their somewhat lower toxicity compared with that of DL-PCBs, NDL-PCBs are classified in the medium potential concern category.

(b) Chemical elements (heavy metals: cadmium, mercury and lead)

Among the chemical elements, heavy metals traditionally have gained attention as contaminants in animal tissues as they may accumulate in certain organs, particularly in kidneys, over the lifespan of an animal. Exposure of animals is commonly related to contaminated feed materials, despite older reports of accidental intoxication of animals due to other sources (paints, batteries). The CONTAM Panel has issued, within the framework of the re-evaluation of undesirable substances in animal feeds according to Council Directive 2002/32/EC, several opinions addressing heavy metals and arsenic in feed materials and the transfer of these elements from feed to edible tissues, milk and eggs.

Cadmium (EFSA, 2009a) is a heavy metal found as an environmental contaminant, both through natural occurrence and from industrial and agricultural sources. Cadmium accumulates in humans and animals, causing concentration-dependent renal tubular damage. Older animals are expected to have higher concentrations of cadmium accumulated in the kidneys. The results from the NRCPs for the

2005–2010 period show that, of the 18 798 bovine samples tested for chemical elements, 324 were non-compliant results for cadmium. Mostly the non-compliant results were kidney samples from cows, but occasionally non-compliant results were found for kidney samples from young animals or in other matrixes (i.e. muscle, liver).

Mercury (EFSA, 2008a, 2012c) exists in the environment as elemental mercury, inorganic mercury and organic mercury (primarily methylmercury). Methylmercury bioaccumulates and biomagnifies along the aquatic food chain. The toxicity and toxicokinetics of mercury in animals and humans depend on its chemical form. Elemental mercury is volatile and mainly absorbed through the respiratory tract, whereas its absorption through the gastrointestinal tract is limited (10–30 %). Following absorption, inorganic mercury distributes mainly to the kidneys and, to a lesser extent, to the liver. The critical effect of inorganic mercury is renal damage.

Data from MS indicated the presence of mercury in animal feeds, but the measured concentrations remained below the maximum content for feed materials (0.1 mg/kg feed according to Directive 2002/32/EC). Human exposure is predominantly associated with fish consumption; bovine meat and offal are assumed to contribute to only a minor extent to human exposure (EFSA, 2008a, 2012c). The results from the NRCPs for the 2005–2010 period show that, of the 18 798 bovine samples tested for chemical elements, 49 were non-compliant results for mercury, mostly being kidney samples.

Lead (EFSA, 2010b) is an environmental contaminant that occurs naturally and, to a greater extent, from anthropogenic activities such as mining and smelting and battery manufacturing. Lead is a metal that occurs in organic and inorganic forms; the latter predominate in the environment. Human exposure is associated particularly with the consumption of cereal grains (except rice), cereal and cereal-based products, potatoes, leafy vegetables and tap water. The contribution of (bovine) meat and offal to human exposure is limited. The results from the NRCPs for the 2005–2010 period show that, of the 18 798 bovine samples tested for chemical elements, 33 were non-compliant results for lead.

Given the toxicological profile of these elements and the results from the NRCPs, these three elements have been allocated to the group of substances of medium potential health concern.

2.3.5.3. Substances classified in the low potential concern category

2.3.5.3.1. Prohibited substances: chlorpromazine and nitroimidazoles

(a) Chlorpromazine

Chlorpromazine is a sedative and is also used against motion sickness and as an anti-emetic in pets. Its use is banned in food-producing animals, including cattle. Chlorpromazine is likely to be available as a black-market substance for illicit use in cattle production. Only three non-compliant results for chlorpromazine were reported from the NRCP for the period 2005–2010 (these were from one MS in 2007), indicating that the substance may be rarely used illicitly in bovine animal production. Chlorpromazine is used as an antipsychotic drug in human therapy and has long-term persistence in humans and numerous side-effects, including the more common ones of agitation, constipation, dizziness, drowsiness, etc. (EMEA, 1996).

Chlorpromazine may be effective as a tranquillizer for cattle but, since only three non-compliant results in one year and in a single MS have been found over a number of years of NRCP testing, chlorpromazine currently is ranked as of low potential concern.

(b) Nitroimidazoles

The 5-nitroimidazoles, dimetridazole, metronidazole and ronidazole, are a group of drugs having antibacterial, antiprotozoal and anticoccidial properties. Due to the potential harmful effects of these drugs on human health – carcinogenicity, mutagenicity, genotoxicity and the occurrence of covalent

binding to macromolecules of metabolites with an intact imidazole structure (EMEA, 1997b) their use in food-producing animals is prohibited in the EU, the USA, China and other countries.

Nitroimidazoles had been used as veterinary drugs for the treatment of cattle, pigs and poultry. Although prohibited for use on food-producing animals, nitroimidazoles are likely to be available on the black-market for illicit use in animal production, particularly since drugs such as metronidazole are readily available as human medicines. However, there are no clinical conditions in cattle for which nitroimidazoles are particularly appropriate. Non-compliant results for nitroimidazoles in cattle have been reported only infrequently in the results from the European NRCPs 2005–2010 (two non-compliant results), suggesting that abuse of nitroimidazoles in cattle production in Europe is not widespread.

Considering that nitroimidazoles have proven toxicity for humans and that they may be effective as antibacterial/antiprotozoal treatments for cattle, these substances might be ranked as of medium potential concern. However, since only occasional non-compliant results have been found over a number of years of NRCP testing, nitroimidazoles currently are ranked as of low potential concern.

2.3.5.3.2. Natural toxins: mycotoxins and toxic plant secondary metabolites

(a) Mycotoxins

Mycotoxins comprise a chemically diverse group of secondary metabolites of moulds which may induce intoxications in humans and animals following ingestion of contaminated food or feed materials. Most of the known mycotoxins are efficiently degraded by the rumen microflora and have a short biological half-life.

Beef animals may be exposed to mycotoxins because of growth of fungi on grass, forages and cereals and during the ensilage process or during storage. Fusarium mycotoxins, such as zearalenone, and trichothecenes have been associated with maize silage and with cereals. While mycotoxins in feed may affect animal health and reduce performance, ruminants are less sensitive to mycotoxins than monogastric animals as, generally, the mycotoxins are degraded to non-toxic metabolites in the rumen.

Mycotoxins evaluated by the CONTAM Panel as undesirable contaminants in animal feeds, including aflatoxins (EFSA, 2004b), deoxynivalenol (EFSA, 2004c), fumonisins (EFSA, 2005b) zearalenone (EFSA, 2004a), T-2 toxin (EFSA, 2011a), and ergot alkaloids (EFSA, 2012d), may pose a risk for animal health and productivity when present in feed materials that are used for bovine animals over an extended period of time. However, most of the known mycotoxins are efficiently degraded by the rumen microflora and have a short biological half-life. Hence, even if residues of mycotoxins are occasionally detected in animal tissues (monogastric animal species) they do not contribute significantly to human exposure, which is mainly related to the consumption of cereal products, nuts and spices. Due to the low number of non-compliant results reported in NRCPs for the 2005–2010 period (15 out of a total of 7 516 samples analysed) and also due to their short half-life, limited transfer into edible tissues (except aflatoxin M_1 into milk) and hence the lack of substantial residues in bovine tissues, these mycotoxins have been assigned to the category of low potential concern.

(b) Toxic plant secondary metabolites (toxic PSMs)

Plants used as feed materials may contain undesirable substances such as toxic PSMs and/or botanic impurities. The most commonly found toxic PSMs have been assessed by the CONTAM Panel within the framework of the re-evaluation of undesirable substances in animal feeds (implementation of Directive 2002/32/EC). The evaluations addressed plant metabolites such as glucosinolates (EFSA, 2008b), saponins (EFSA, 2009b), pyrrolizidine alkaloids (EFSA, 2007a, 2011b), tropane alkaloids (EFSA, 2008c) and cyanogenic compounds (EFSA, 2007b) as well as a number of individual substances, such as theobromine (EFSA, 2008d), gossypol (EFSA, 2008e) and ricin (EFSA, 2008f).

While for several of these substances potential concerns for animal health could be identified following ingestion with feed, none of these natural toxins appeared to accumulate in edible tissues. The limited data on the kinetics of these metabolites do not preclude in all cases a transfer from the feed into animal tissues under certain circumstances of exposure. For example, residues of gossypol in meat of cattle (and sheep) were demonstrated under experimental conditions (feeding of cotton meal as main feed component), but such residues are not expected under the conditions of European farming, where cotton seeds or cotton seed by-products are infrequently used and only with limited inclusion rates in feed (EFSA, 2008e). Other natural substances, such as the fungal metabolite (mycotoxin) zearalenone, are intensively metabolized in the rumen and following absorption in the liver and other animal tissues, and this may explain certain non-compliant analytical results. Zearalanol (zeranol) is one of these metabolites and is used in certain Third Countries as a growth promoting agent due to its estrogenic activity (see Section 2.3.5.2.1 (d) in this document). This applies also to certain thiocyanates and oxazolidinethiones, originating from glycosinolates produced by a broad variety of plants of the Brassicaceae family. They target different steps in the synthesis of thyroid hormones, leading eventually to hypothyroidism and enlargement of the thyroid gland (goitre) (EFSA, 2008b). Again, these natural products may explain some of the non-compliant results found in NRCP testing where treatment of animals with antithyroid agents (thyreostats) has been suspected.

Recently, an increasing use of herbal remedies, given as so-called alternatives to antibiotics for animals, has been reported also in ruminants. Many of the herbal products contain biologically active substances that are also addressed in the list of undesirable plant metabolites. However, the remedies are given in low concentrations (lower than the larger amount that could be ingested with feed), and for a limited period. Although specific data are lacking, it seems unlikely that residues of these compounds may be found in edible tissues of slaughter animals. Such substances, therefore, are placed in the category of low potential concern within the current classification.

2.3.5.3.3. Contaminants: organochlorine pesticides and organophosphorus compounds

(a) Organochlorine compounds

Organochlorine pesticides, such as dichlorodiphenyltrichloroethane (DDT) and its metabolites, hexachlorocyclohexanes (HCHs), dieldrin and toxaphene, have been assigned to the category of contaminants of low potential concern. The occurrence of residues of these substances has declined over the years, because of their long-standing ban, and relatively low levels in animal products can be expected, as shown by results from the NRCPs 2005–2010, which indicate that six results out of the total of 17 350 samples tested for the category of organochlorine compounds were non-compliant for organochlorine pesticides.

(b) Organophosphorus compounds

Organophosphorus compounds are classified in Council Directive 96/23/EC as Group B3b contaminants although they may also be used as VMPs (as antiparasitic agents) in bovine animals. However, their infrequent use and short half-life results in these compounds being assigned to the category of low potential concern, or even negligible potential concern where MRLs are not exceeded. The results from the NRCPs from 2005–2010 indicate that two out of the total of 10 826 samples tested for the category of organophosphorus compounds were non-compliant.

2.3.5.3.4. VMPs and feed additives above MRLs, including corticosteroids

VMPs, such as antimicrobials, anticoccidials and antiparasitics, are commonly used in bovine animals for prophylactic purposes, particularly at the beginning of the fattening period and prior to turning animals out to grazing (anti-parasitic treatments). Therapeutic use of VMPs, particularly antimicrobials, may occur in response to diagnosis of infection in individual animals or in the herd.

Bovine animals may enter the food market following casualty slaughter at various ages, coming from beef production systems, dairy herds and beef suckler herds. These animals may represent a possible risk in terms of elevated residues of VMPs due to prior treatments and the unscheduled nature of their slaughter. The legal definition of emergency slaughter is the slaughter of healthy animals which have suffered an accident. However, the interpretation of accident and emergency is not always clear (Parker and Hinton, 1990; Aldiss, 2007; Sarnago Coello et al., 2007).

In general, VMPs, except the substances allocated to Table 2 of Regulation (EC) No 37/2010, are categorised as being of low potential concern because they have all been subjected to pre-marketing approval which specifies ADIs, and MRLs, with the aim of guaranteeing a high level of safety to the consumer. Where exceedances of MRLs are found in the residue monitoring programmes (i.e. 434 non-compliant results for antibacterials out of the 154 773 tested samples; 17 non-compliant results for anthelmintics out of the 34 895 tested samples, 55 non-compliant results for NSAIDs out of the 28 476 tested samples and 10 non-compliant results for anticoccidials out of the 8 585 tested samples), these are typically of an occasional nature that is not likely to constitute a concern to public health.

(a) Corticosteroids

Corticosteroids are steroid hormones produced by the adrenal cortex and are used for a range of therapies in both humans and animals. A number of synthetic corticosteroids, i.e. betamethasone, dexamethasone, methylprednisolone and prednisolone, are approved for use as VMPs in bovine animals and, therefore, have associated withdrawal periods and MRLs. In addition to their therapeutic uses, corticosteroids, when used at low dosages, are reported to increase appetite, weight gain and feed efficiency, as well as skeletal muscle mass and carcass characteristics (Courtheyn et al., 2002; Tarantola et al., 2004; Carraro et al., 2009).

Table 7 shows the data for non-compliant results for corticosteroids in bovine samples in the NRCP for the period 2005–2010. A total of 345 non-compliant results were recorded overall, with dexamethasone representing the corticosteroid determined most in each year of testing and prednisolone occurring as the next most frequent substance.

Table 7: Data for corticosteroids: 345 non-compliant results from the NRCPs for the period 2005–2010 (data already included in Tables 3 and 4 as Group A3 (Italy and the Netherlands) or Group B2f (all other MSs)). The number of MSs providing data on non-compliant results is shown in brackets.

Non-compliant results	2010 (EU-27)	2009 (EU-27)	2008 (EU-27)	2007 (EU-27)	2006 (EU-27)	2005 (EU-25)
Corticosteroids	56	48	56	51	74	60
Betamethasone	1 (1)				1 (1)	1 (1)
Dexamethasone	48 (5)	33 (7)	39 (7)	41 (7)	67 (4)	56 (8)
Prednisolone	6 (3)	16(4)	11 (2)	8 (3)	5 (2)	3 (1)
Prednisone	1 (1)	3 (2)	3 (1)			
Methylprednisolone			2 (2)	2 (2)	1 (1)	
Triamcinolone acetonide			1 (1)		1 (1)	

The relatively high incidence of non-compliant results points to potential abuse of corticosteroids for growth promotion in cattle and possibly to misuse as medicinal agents. Synthetic compounds, most notably dexamethasone, betamethasone, and methylprednisolone, display a powerful glucocorticoid action which is many times greater than that of their natural counterparts (cortisol and cortisone), being also able to accumulate at the injection site and in liver to levels ranging from a few ppb to > 100 ppb (EC, 2010). Since very low ADIs have been established for compounds accounting for most of the non-compliant results (i.e. 0.015 µg/kg b.w., corresponding to 0.9 µg active principle/day, for both dexamethasone and betamethasone), the potential for adverse effects for consumers cannot be excluded. Dexamethasone and betamethasone are teratogenic in experimental animals by the oral

route (EMEA, 1997c, 1999a), are able to cross both the placental and mammary barriers and may significantly increase blood glucose levels in diabetics (Refuerzo et al., 2012). In addition, both prenatal (Seckl and Holmes, 2007) and perinatal (Raff, 2004) exposure to glucocorticoids have been associated with a number of adverse effects including reduced birth size, insulin resistance as well as metabolic and neurological disorders. In contrast to dexamethasone and related fluorinated glucocorticoid steroids, trace amounts of urinary prednisolone may occur as an endogenous substance likely originating from the stress hormone (cortisone/cortisol)-related pathways (Vincenti et al., 2012).

In conclusion, considering that corticosteroids are licensed VMPs and that exceedances of MRLs in samples have been found in the NRCPs for 2005–2010, these substances are ranked in the category of low potential concern. This ranking is in the context of corticosteroids, generally, being used appropriately as VMPs. However, because of the increasing evidence for the abuse of these compounds as growth promoting agents, control measures should focus on preventing the potential illicit use of these substances in bovine production in the EU.

2.3.5.4. Substances classified in the negligible potential concern category

In the negligible potential concern category are the dyes and the prohibited substances, colchicine, dapsone, chloroform and *Aristolochia* spp.

2.3.5.4.1. Prohibited substances: colchicine, dapsone, chloroform and *Aristolochia* spp.

(a) Colchicine

Colchicine is a plant alkaloid that has been used in veterinary medicine to treat papillomas and warts in cattle and horses by injection at the affected area. A possible contamination of food with colchicine has been identified through consumption of *Colchicum autumnale* in forage by animals such as cattle or sheep and, in this context, colchicine has been determined in milk of sheep after exposure to *C. autumnale* (Hamscher et al., 2005). Colchicine is genotoxic and teratogenic and may have toxic effects on reproduction.

No non-compliant results for colchicine in bovine animals have been reported from the European NRCPs 2005–2010; however, it is probable that testing for this substance may not be included in monitoring programmes in many countries.

In the absence of evidence for use of colchicine in bovine animal production, colchicine currently is ranked as of negligible potential concern.

(b) Dapsone

Dapsone is a drug used in humans and formerly in veterinary medicine; in human medicine for treatment of leprosy, malaria, tuberculosis and dermatitis, and in veterinary medicine as an intra-mammary treatment for bovine mastitis, for oral treatment of bovine coccidiosis and for intra-uterine treatment of endometriosis. Following scientific assessment by the Committee for Medicinal Products for Veterinary Use (CVMP) (EMEA, 1999b), a provisional MRL of 25 µg/kg parent drug was established for muscle, kidney, liver, fat and milk for all food-producing animals. Further information on teratogenicity and reproductive effects for dapsone was required but, when this was not provided, the substance was recommended for inclusion in Annex IV to Council Regulation (EEC) No 2377/90 (now Table 2 of Commission Regulation (EU) No 37/2010). Dapsone has a number of potentially harmful side-effects in humans when given at therapeutic doses as a human medicine. More recently, the CVMP has reviewed the alleged mutagenicity of dapsone in the context of its occurrence as an impurity in VMPs containing sulphonamides and concluded that it is not genotoxic (CVMP, 2012), and EFSA has issued an Opinion on the product as a food packaging material (compound 15267), proposing an acceptable level of 5 mg/kg food (EFSA, 2005c). No non-compliant results for dapsone in bovine animals have been reported from the European national residue control plans 2005–2010.

However, a review of testing carried out in MS during 2008 by the Community Reference Laboratory AFSSA (Agence Française de Sécurité Sanitaire des Aliments, Fougères, France) found that testing for dapsone in bovine animals was carried out in only 6 countries.

In the absence of evidence for use of dapsone in bovine animal production, dapsone currently is ranked as of negligible potential concern.

(c) Chloroform and *Aristolochia* spp.

In the negligible potential concern category are the prohibited substances, chloroform and plant remedies containing *Aristolochia* species, as these are not relevant to bovine animal production and there is no evidence for use of these substances in bovine animal production.

2.3.5.4.2. VMPs below MRLs: carbamates and pyrethroids, sedatives

VMPs used in bovine animal production but with no evidence for residues above MRLs being found in monitoring programmes as well as those VMPs irrelevant for bovine animal production are ranked as of negligible potential concern.

(a) Carbamates and pyrethroids

Carbamates and pyrethroids are used in animal houses and occasionally in animals, including bovine animals, for control of environmental infections, such as lice eggs in buildings. There are no recent incidents of non-compliant results reported in NRCP testing in bovine animals during the period 2005–2010, resulting in these substances being assigned to the category of negligible potential concern.

(b) Sedatives

A range of sedative substances including barbiturates, promazines, xylazine and ketamine, are licensed for use in bovine animals and other animal species for sedation and analgesia during surgical procedures or for euthanasia. They are rarely used in bovine animals. In one single year 10 non-compliant results have been reported (nine promazine and one acepromazine) out of the 14 210 total samples analysed under the NRCPs 2005–2010. Owing to their rapid excretion, these substances generally do not have detectable residues in muscle and so do not have MRLs registered in the EU. Animals euthanized with these substances are not allowed to enter the food chain. However, it should be noted that testing for this category of substances is not required under the provisions of Council Directive 96/23/EC.

2.3.5.4.3. Contaminants: dyes

There are no indications for use of dyes such as (leuco-)malachite green in bovine animals. Testing of bovine animals for this group of substances is not required under Council Directive 96/23/EC.

A summary of the outcome of the ranking is presented in Table 8.

Table 8. Ranking of chemical residues and contaminants in bovine animals based on pre-defined criteria and taking into account the findings from the NRCPs for the period 2005–2010.

Group / Potential concern category	Prohibited substances	VMPs and licensed feed additives	Contaminants
Category1 **Negligible potential concern**	• *Aristolochia spp.* • Chloroform • Colchicine • Dapsone	• VMPs below MRLs	• Dyes
Category 2 **Low potential concern**	• Chlorpromazine • Nitroimidazoles	• VMPs exceeding MRLs, including corticosteroids	• Organochlorine pesticides • Organophosphorus compounds • Chemical elements (feed supplements) • Natural toxins (mycotoxins and PSMs)
Category 3 **Medium potential concern**	• Stilbenes • Thyreostats • Gonadal steroids • Resorcylic acid lactones • Beta-agonists (esp. clenbuterol) • Chloramphenicol • Nitrofurans		• NDL-PCBs • Chemical elements (Cadmium, Mercury and Lead).
Category 4 **High potential concern**			• Dioxins • DL-PCBs

MRL, maximum residue limit; NRCP, national residue control plan; PSM, plant secondary metabolite; VMP, veterinary medicinal product.

2.3.5.5. Future aspects

The ranking into specific categories of potential concern of prohibited substances, VMPs and contaminants presented in this section applies exclusively to bovine animals and is based on current knowledge regarding the toxicological profiles, usage in bovine animal production, and occurrence as residues or contaminants, as demonstrated by the data from the NRCPs for the 2005–2010 period. Where changes in any of these factors occur, the ranking might need amendment.

2.3.5.5.1. New hazards

Another element of future aspects is the issue of 'new hazards'. In this context, new hazards are defined as compounds that have been identified as anthropogenic chemicals in food-producing animals and derived products and in humans and for which occurrence data are scarce. It does not imply that there is evidence for an increasing trend in the concentration of these compounds in food or in human samples. Examples are brominated flame retardants, such as polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs) or perfluorinated compounds, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

(a) Polybrominated diphenyl ethers (PBDEs)

In 2011, EFSA performed a risk assessment on polybrominated diphenyl ethers (PBDEs) in food (EFSA, 2011d). PBDEs are additive flame retardants which are applied in plastics, textiles, electronic castings and circuitry. PBDEs are ubiquitously present in the environment and likewise in biota and in food and feed. Eight congeners were considered by the CONTAM Panel to be of primary interest: BDE-28, -47, -99, -100, -153, -154, -183 and -209. The highest dietary exposure is to BDE-47 and

-209. Toxicity studies were carried out with technical PBDE mixtures or individual congeners. The main targets were the liver, thyroid hormone homeostasis and the reproductive and nervous systems. PBDEs are not genotoxic. The CONTAM Panel identified effects on neurodevelopment as the critical endpoint, and derived benchmark doses (BMDs) and their corresponding lower 95 % confidence limits for a benchmark response of 10 %, the $BMDL_{10}$s, for a number of PBDE congeners: BDE-47, 309 µg/kg b.w.; BDE-99, 12 µg/kg b.w.; BDE-153, 83 µg/kg b.w.; BDE-209, 1 700 µg/kg b.w. Owing to the limitations and uncertainties in the current database, the Panel concluded that it was inappropriate to use these BMDLs to establish health based guidance values, and instead used a margin of exposure (MOE) approach for the health risk assessment. Since elimination characteristics of PBDE congeners in animals and humans differ considerably, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that for BDE-47, -153 and -209 current dietary exposure in the EU does not raise a health concern. For BDE-99 there is a potential health concern with respect to current dietary exposure. The contribution of bovine meat and bovine derived products to total human exposure is currently unknown. As these compounds bioaccumulate in the food chain, they deserve attention and should be considered for inclusion in the NRCPs.

(b) Hexabromocyclododecanes (HBCDDs)

In 2011, EFSA delivered a risk assessment on hexabromocyclododecanes (HBCDDs) in food (EFSA, 2011e). HBCDDs are additive flame retardants primarily used in expanded and extruded polystyrene applied as construction and packing materials, and in textiles. Technical HBCDD consists predominantly of three stereoisomers (α-, β- and γ-HBCDD). Also δ- and ε-HBCDD may be present but at very low concentrations. HBCDDs are present in the environment and likewise in biota and in food and feed. Data from the analysis of HBCDDs in 1 914 food samples were provided to EFSA by seven European countries, covering the period from 2000 to 2010. The CONTAM Panel selected α-, β- and γ-HBCDD as being of primary interest. Since all toxicity studies were carried out with technical HBCDD, a risk assessment of individual stereoisomers was not possible. The main targets were the liver, thyroid hormone homeostasis and the reproductive, nervous and immune systems. HBCDDs are not genotoxic. The CONTAM Panel identified neurodevelopmental effects on behaviour as the critical endpoint, and derived a benchmark dose lower confidence limit for a benchmark response of 10 % ($BMDL_{10}$) of 0.79 mg/kg b.w. Owing to the limitations and uncertainties in the current database, the CONTAM Panel concluded that it was inappropriate to use this BMDL to establish a health-based guidance value, and instead used a margin of exposure (MOE) approach for the health risk assessment of HBCDDs. Since elimination characteristics of HBCDDs in animals and humans differ, the Panel used the body burden as starting point for the MOE approach. The CONTAM Panel concluded that current dietary exposure to HBCDDs in the EU does not raise a health concern.

The occurrence data reported to EFSA have shown that HBCDDs could be detected in a limited number of meat samples. As the total number of bovine meat samples analysed for HBCDDs are sparse and thus the current knowledge about the prevalence and their levels in edible tissues of bovine animals is limited, an inclusion into the NRCPs even as a temporary measure should be considered.

(c) Perfluorinated compounds (PFCs)

Perfluorinated compounds (PFCs), such as PFOS, PFOA and others, have been widely used in industrial and consumer applications including stain- and water-resistant coatings for fabrics and carpets, oil-resistant coatings for paper products approved for food contact, fire-fighting foams, mining and oil well surfactants, floor polishes and insecticide formulations. A number of different perfluorinated organic compounds have been widely found in the environment. In 2008, EFSA delivered a risk assessment on PFOS and PFOA in food (EFSA, 2008g). The CONTAM Panel established a tolerable daily intake (TDI) for PFOS of 150 ng/kg b.w. per day and a TDI for PFOA of 1.5 µg/kg b.w. per day. A few data indicated the occurrence of PFOS and PFOA in meat samples. However, due to the low number of data, it has not been possible to perform an assessment of the relative contribution from different foodstuffs to human exposure to PFOS and PFOA. A recent study where contaminated feed was fed to cows demonstrated the transfer of PFOS, PFOA and various other

perfluorinated compounds with different chain lengths into meat and various organs of the cows (Ehlers, 2012). As perfluorinated compounds have found widespread use and ubiquitous distribution in the environment, but representative data on their occurrence in meat are still limited, an intensified monitoring of these compounds in tissues, as well as in feed, should be considered.

(d) Chemical elements (feed supplements)

In addition to the heavy metals discussed in Section 2.3.5.2.2, attention should be given to those compounds that may be used as feed supplements (e.g. copper, selenium, zinc). The correct use of these supplements cannot be guaranteed. Copper, in particular, may be given in excess via feed supplements, resulting in non-compliant feed samples and undesirable residues in animal organs, such as the liver. A closer communication of results from official feed control seems essential to decide whether or not analytical monitoring of residues in slaughter animals needs to be directed to these substances that might be overused in bovine feeds.

3. TOR 2: Strengths and weaknesses of the current meat inspection methodology

In light of the existing regulation and the daily practice of the control of residues/chemical substances in bovine carcasses, the strengths and weaknesses of the current meat inspection methodology can be summarised as follows.

3.1. Strengths of the current meat inspection methodology for chemical hazards

The strengths of the current meat inspection methodology for chemical hazards are as follows:

- The current procedures for sampling and testing are a mature system, well established, coordinated, and subject to regular evaluation that is in place across EU MSs, with residue testing that is based on common standards for method performance and interpretation of results (Commission Decision 2002/657/EC), laboratory accreditation (ISO/IEC 17025) and quality assurance schemes (QAS). The residue monitoring programmes are supported by a network of EU and National Reference Laboratories and by research in the science of residue analysis that serves to provide state-of-the-art testing systems for control of residues (see Annex A).

- There are well-developed systems and follow-up actions subsequent to the identification of non-compliant samples. As indicated in Section 1.5, follow-up on non-compliant samples is typically through intensified sampling (suspect sampling), withholding of slaughter and/or of carcasses subject to positive clearance as compliant, and on-farm investigations potentially leading to penalties and/or criminal prosecutions.

- The system is generally well endorsed by sector stakeholders throughout the food chain (national farmers associations, feed/meat industry, retailers).

- The regular sampling and testing for chemical residues is a disincentive to the development of bad practices. There is constant development of new approaches in sampling and testing methodologies, particularly in the area of prohibited substances, directed at identifying illicit use of such substances in animal production; for example, use of samples other than edible tissues, such as excreta, eyes, hair, etc. that demonstrate enhanced residue persistence characteristics, and use of indirect testing procedures, such as genomics, proteomics and metabolomics, to identify treated animals.

- The prescriptive sampling system allows for equivalence in the control of EU produced veal/beef. Any forthcoming measures have to ensure that the control of imports from Third Countries remains equivalent to the controls within the domestic market (this issue is addressed further in TOR 4).

- The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring. However, any indication of misuse or abuse of pharmacologically active substances through visual assessment needs to be confirmed by chemical analysis for potential residues.

3.2. Weaknesses of the current meat inspection methodology for chemical hazards

The weaknesses of the current meat inspection methodology for chemical hazards are as follows:

- With very few exceptions, chemical hazards cannot be detected by current *ante-/post-* mortem meat inspection procedures, indicating the need for further harmonization of risk reduction strategies along the entire food chain.

- At present, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs in terms of communication and follow-up testing strategies or interventions.

- Under the current system, sampling is mostly prescriptive rather than risk or information based. It appears that individual samples taken under the NRCP testing programme may not always be taken as targeted samples, as specified under Council Directive 96/23/EC, but sometimes may be taken as random samples. There is a lack of sufficient cost-effective and reliable screening methods and/or the range of substances prescribed/covered by the testing is sometimes limited.

- There is limited flexibility to adopt new chemical substances into the NRCPs and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes.

- The sampling under the NRCPs reflects only a part of testing done by a number of MSs and, therefore, data from the NRCPs may not provide the most complete information for certain categories of substances.

4. TOR 3: New hazards

Current monitoring of residues and contaminants in edible tissues of slaughter bovine animals is based on Council Directive 96/23/EC. In turn, risk ranking, as presented under TOR 1, is also based largely on the chemical substances listed in Council Directive 96/23/EC. The outcome of the ranking showed that only a small number of compounds are considered to constitute a high potential concern for consumers.

However, considering the recent information available from the reassessment of undesirable substances in the food chain, covered by more recent EFSA opinions of the CONTAM Panel, additional compounds have been identified that require attention. Prominent examples of such substances are dioxins and DL-PCBs, which were identified as high potential concern compounds as they bioaccumulate in the food chain, are likely to be found in bovine carcasses and have a toxicological profile that points towards public health concerns even at low (residue) concentrations. In addition, it has been shown that these substances are found in edible tissues of bovine animals. Other halogenated substances, such as brominated flame retardants, including polybrominated diphenylethers (PBDEs), as well as hexabromocyclododecanes (HBCDDs) and perfluorinated compounds (PFCs), such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), have a different toxicological profile. These compounds bioaccumulate in the food chain and deserve attention, as currently the knowledge about the prevalence and level of residues of these compounds in edible tissues of bovine animals is limited. Chemical elements, such as copper, selenium and zinc, given as feed supplements may be subject to overuse in bovine feeds resulting in non-compliant feed samples and undesirable residues in animal organs, such as the liver.

Inclusion of these various substances in the NRCPs (even as a temporary measure) should be considered together with an intensified monitoring of feed materials for the presence of these compounds, to support forthcoming decisions on whether or not these substances require continued monitoring either in feed materials and/or in slaughter animals.

New technologies such as the production of bioethanol and biodiesel, and the increasing availability of new by-products suitable for inclusion in animal feeds from these technical processes, such as for example distillers dried grains (DDGs), need to be addressed in hazard identification and subsequently may require new testing strategies and methods (see also TOR 4). In addition, as a consequence of the emerging need for plant (vegetable) oils in bioethanol production, processing aids and toxic plant metabolites (such as gossypol) may (re)appear in the food chain.

5. TOR 4: Adaptation of inspection methods

Bovine farming in the EU is diverse, with substantial differences between intensively and extensively produced animals and between veal calves and adult bovine animals. Consequently, the types and likelihood of occurrence of chemical residues and contaminants will vary. While no species-specific chemical risks for buffalo were identified, similar exposure to environmental contaminants may be considered to apply as for outdoor cattle.

In many cases, veal calves are intensively reared and the same is true for fattening bulls, while steers and heifers for meat production, generally, are reared extensively. For heifers and cows in dairy production, the keeping practices are different, depending on the region and the farm type.

Veal calf production occurs at a larger scale in a limited number of MS (EFSA, 2012a). Such farms often operate under the standards of Good Farming Practice (GFP) and Good Hygiene Practice (GHP) and with HACCP-based protocols in place, providing detailed Food Chain Information (FCI). Consequently, under the current prescriptive residue control plans, integrated farms delivering large numbers of animals in one shipment for slaughter may be oversampled, while extensive veal and beef production farms delivering small numbers of animals may be undersampled. It is recommended that the frequency of sampling for farms should be adjusted to the FCI presented.

In contrast to fully integrated veal calf production farms, for calves coming from suckler herds or from dairy farms usually only limited and incomplete FCI data can be provided. Additionally, for bovine animals produced in extensive systems, the FCI should be expanded to provide more information on the specific environmental conditions of the farms where the animals are produced. It is recommended that sampling of bovine animals should be based on the types and likelihood of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

To achieve better integration of results from official feed control with residue monitoring seems essential to indicate whether monitoring of residues in slaughter animals needs to be directed to particular substances. Therefore, there is a need for an improved integration of sampling, testing and intervention protocols across the food chain, NRCPs, feed control and monitoring of environmental contaminants.

In addition, there is a need to develop new approaches to testing. Recent developments in chemical analytical techniques allow the simultaneous measurement of a broad range of substances. Analytical techniques covering multiple analytes and of new biologically based testing approaches should be incorporated into feed quality control and NRCP testing. Application of such validated methods for multi-residue analyses, comprising veterinary drugs, pesticides and natural and environmental contaminants, should be encouraged.

For prohibited substances, testing should be directed towards the farm level. One of the limitations of the currently applied analytical strategies is the generally poor sensitivity of some screening methods, resulting in the potential failure to detect residues in the low µg/kg range and therefore to identify non-

compliant samples. New approaches including molecular biological techniques for the identification of indirect biomarkers of exposure in animals, as well as the development of reliable *in vitro* assays based on the biological action(s) of the compounds under analysis, are considered to be of additional value. Such approaches may help in detecting molecules of unknown structure or not included in the NRCPs but sharing a common mechanism of action, thereby better orienting and rationalising the subsequent chemical analysis.

In the case of many of the substances that might be used illicitly for growth promoting purposes in bovine production, the results of NRCP testing show no non-compliant results (e.g. stilbenes) or indicate that many of the non-compliant results reported are due to dietary sources (e.g. thyreostats, zeranol) or are due to endogenous production (e.g. gonadal (sex) steroids). Therefore, future NRCP testing relating to such substances needs to be reduced and/or refocused in terms of the range of analytes tested and the appropriateness of samples taken for testing—to better identify the extent of abuse of growth-promoting substances in bovine production in the EU. In addition, control measures for such substances must not rely exclusively on NRCP testing, but should include veterinary inspection/police activities along the food chain directed at identifying abuse of such substances in bovine production in the EU.

Finally, it should be noted that any measures taken to improve the efficacy of meat inspection protocols need to address also the compliance of imports to the EU with these strategies. Where EU meat inspection would move to a risk-based approach, particular attention to the achievement of equivalent standards of food safety for imported food from Third Countries will be required. Currently, within the prescriptive system for meat inspection and residue monitoring in the EU, Third Countries exporting food products of animal origin to the EU need to demonstrate that they have the legal controls and residue monitoring programmes capable of providing equivalent standards of food safety as pertains within the EU. If EU meat inspection moves to a risk-based approach, particular attention to the achievement of equivalent standards of food safety for imported food from Third Countries will be required. The risk-ranking appropriate within the EU in relation to veterinary drugs and contaminants might not be appropriate in Third Countries to achieve equivalent standards of food safety. Rather than requiring that a risk-based monitoring programme applying within EU MS should be applied similarly in the Third Country, an individual risk assessment for each animal product(s)/Third Country situation may be required, which should be updated on a regular basis.

CONCLUSIONS AND RECOMMENDATIONS

This section contains Conclusions derived from the information discussed in the document, together with Recommendations for improvements to meat inspection with regard to chemical hazards within the European Union (EU).

TOR 1. To identify and rank the main risks for public health that should be addressed by meat inspection at EU level. General (e.g. sepsis, abscesses) and specific biological risks as well as chemical risks (e.g. residues of veterinary drugs and contaminants) should be considered. Differentiation may be made according to production systems and age of animals (e.g. breeding compared to fattening animals).

CONCLUSIONS

- As a first step in the identification and ranking of chemical substances of potential concern, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) considered the substances listed in Council Directive 96/23/EC and evaluated the outcome of the national residue control plans (NRCPs) for the period 2005–2010. The CONTAM Panel noted that only 0.25 % of the total number of results was non-compliant for one or more substances listed in Council Directive 96/23/EC. Potentially higher exposure of consumers to these substances from bovine meat takes place only incidentally, as a result of mistakes or non-compliance with known and regulated procedure. The available aggregated data indicate the

number of samples that were non-compliant with the current legislation. However, in the absence of substance-specific information, such as the tissues used for residue analysis and the actual concentration of a residue or contaminant measured, these data do not allow for a reliable assessment of consumer exposure.

- Other criteria used for the identification and ranking of chemical substances of potential concern included the identification of substances that are found in other testing programmes, that bioaccumulate in the food chain, substances with a toxicological profile of concern, and the likelihood that a substance under consideration will occur in bovine carcasses. Taking into account these criteria, the individual compounds were ranked into four categories denoted as of high, medium, low and negligible potential concern.

- The highest overall proportion of non-compliant results under the NRCPs were for Group B3 substances, contaminants (0.95 %) representing largely exceedances of the maximum levels/maximum residue limits (MLs/MRLs) specified for these substances. The proportion of non-compliant results overall for Group A substances, prohibited substances (0.19 %) and for Group B1/B2 substances, veterinary medicinal products (VMPs) (0.22 %) represent largely illicit use and exceedances of the MRLs, respectively.

- Dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) were ranked as being of high potential concern due to their known bioaccumulation in the food chain, the risk of exceedance of MLs, and in consideration of their toxicological profile.

- Stilbenes, thyreostats, gonadal (sex) steroids, resorcylic acid lactones and beta-agonists, especially clenbuterol, were ranked as being of medium potential concern because of their toxicity to humans, their efficacy as growth promoters in cattle and the incidence of non-compliant results.

- Chloramphenicol and nitrofurans were ranked as being of medium potential concern, as they have proven toxicity for humans, are effective as antibacterial treatments for cattle and residues in bovine carcasses have been found from the NRCPs in various MS.

- Non-dioxin-like polychlorinated biphenyls (NDL-PCBs) bioaccumulate and there is a risk for exceedance of the MLs, but they were ranked in the category of medium potential concern because they are less toxic than dioxins and DL-PCBs.

- The chemical elements cadmium, lead and mercury were allocated to the medium potential concern category taking into account the number of non-compliant results reported under the NRCPs and their toxicological profile.

- Residues originating from other substances listed in Council Directive 96/23/EC were ranked as of low or negligible potential concern due to the toxicological profile of these substances at residue levels in edible tissues, or to the very low or non occurrence of non-compliant results in the NRCPs 2005–2010, and/or to the natural occurrence in bovine animals of some of these substances.

- The low potential concern category includes chlorpromazine, nitroimidazoles, organochlorine pesticides, organophosphorus compounds, mycotoxins, toxic plant secondary metabolites, as well as VMPs exceeding MRLs.

- In the negligible potential concern category are the prohibited substances colchicine, dapsone, chloroform and *Aristolochia* spp., the dyes, as well as VMPs occurring below MRLs.

- The CONTAM Panel emphasises that this ranking into specific categories of potential concern is based on current knowledge regarding toxicological profiles, usage in bovine animal production and occurrence as contaminants or chemical residues, as demonstrated by the data from the NRCPs for the 2005–2010 period.

RECOMMENDATIONS

- Future monitoring programmes should be risk based, taking into account the ranking of chemical compounds into categories of potential concern.

- Regular updating of the ranking of chemical compounds in bovine animals as well as of the sampling plans should occur, taking into account any new information regarding the toxicological profile of chemical residues and contaminants, usage in bovine animal production, and actual occurrence of individual substances as residues and contaminants in bovine animals.

TOR 2. To assess the strengths and weaknesses of the current meat inspection methodology and recommend possible alternative methods (at *ante-mortem* or *post-mortem* inspection, or validated laboratory testing within the frame of traditional meat inspection or elsewhere in the production chain) at EU level, providing an equivalent achievement of overall objectives; the implications for animal health and animal welfare of any changes suggested in the light of public health risks to current inspection methods should be considered.

CONCLUSIONS

Strengths of the current meat inspection methodology for chemical hazards are as follows:

- The current procedures for sampling and testing are a mature system, in general well established and coordinated including follow-up actions subsequent to the identification of non-compliant samples. In addition, the identification system for bovine animals provides full transparency of the EU bovine stock.

- The regular sampling and testing for chemical residues and contaminants in the system is an important disincentive to the development of undesirable practices.

- The prescriptive sampling system allows for equivalence in the control of EU veal/beef. Any forthcoming measures have to ensure that the control of imports from Third Countries remains equivalent to the controls within the domestic market.

- The current combination of animal traceability, *ante-mortem* inspection and gross tissue examination can support the collection of appropriate samples for residue monitoring.

Weaknesses of the current meat inspection methodology for chemical hazards are as follows:

- With very few exceptions, presence of chemical hazards cannot be identified by current *ante-/post- mortem* meat inspection procedures at the slaughterhouse level, indicating the need for further harmonisation of risk reduction strategies along the entire food chain.

- At present, there is poor integration between the testing of feed materials for undesirable substances and the NRCPs in terms of communication and follow-up testing strategies or interventions.

- Under the current system, sampling is mostly prescriptive rather than risk or information based. It appears that individual samples taken under the NRCP testing programme may not

always be taken as targeted samples, as specified under Council Directive 96/23/EC, but sometimes may be taken as random samples.

- There is a lack of sufficient cost-effective and reliable screening methods and/or the range of substances prescribed/covered by the testing is sometimes limited.

- There is limited flexibility to adopt emerging chemical substances into the NRCPs and limited ongoing adaptation of the sampling and testing programme to the results of the residue monitoring programmes. In addition, sampling under the NRCPs reflects only a part of testing done by a number of MS, the results of which should be taken into consideration.

RECOMMENDATION

- Meat inspection systems for chemical residues and contaminants should be less prescriptive and should be more risk and information based, with sufficient flexibility to adapt the residue monitoring programmes to results of testing.

TOR 3. If new hazards currently not covered by the meat inspection system (e.g. *Salmonella*, *Campylobacter*) are identified under TOR 1, then recommend inspection methods fit for the purpose of meeting the overall objectives of meat inspection. When appropriate, food chain information should be taken into account.

CONCLUSIONS

- Dioxins and DL-PCBs which accumulate in food-producing animals have been ranked as being of high potential concern. As these compounds have not yet been comprehensively covered by the sampling plans of the current meat inspection (NRCPs), they should be considered as 'new' hazards.

- In addition, for a number of chemical elements used as feed supplements and for organic contaminants that may accumulate in food-producing animals, only limited data regarding residues in bovine animals are available. This is the case, in particular, for brominated flame retardants, including polybrominated diphenylethers (PBDEs) and hexabromocyclododecanes (HBCDDs), as well as perfluorinated compounds (PFCs) including (but not limited to) perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

RECOMMENDATION

- Control programmes for residues and contaminants should include 'new hazards' and take into account information from environmental monitoring programmes which identify chemical hazards to which animals may be exposed.

TOR 4. To recommend adaptations of inspection methods and/or frequencies of inspections that provide an equivalent level of protection within the scope of meat inspection or elsewhere in the production chain that may be used by risk managers in case they consider the current methods disproportionate to the risk, e.g. based on the ranking as an outcome of terms of reference 1 or on data obtained using harmonised epidemiological criteria. When appropriate, food chain information should be taken into account.

CONCLUSION

- Bovine farming in the EU is diverse, with substantial differences between intensively and extensively produced animals, and between veal calves and adult bovine animals, and consequently the types and likelihood of occurrence of chemical residues and contaminants will vary.

RECOMMENDATIONS

- Sampling of bovine animals should be based on the types and likelihood of occurrence of chemical residues and contaminants and on the completeness and quality of the FCI supplied.

- There is a need for an improved integration of sampling, testing and intervention protocols for bovine animals across the food chain, NRCPs, feed control and monitoring of environmental contaminants.

- The development of analytical techniques covering multiple analytes and of new biologically based testing approaches should be encouraged and incorporated into feed quality control and chemical residues and contaminants testing in the NRCPs.

- For prohibited substances, testing should be directed where appropriate towards the farm level. Future NRCP testing relating to substances that might be used illicitly for growth promoting purposes needs to be refocused to better identify the extent of abuse in the EU. In addition, control measures for prohibited substances should not rely exclusively on NRCP testing, but should include veterinary inspection during the production phase and the use of biological methods and biomarkers suitable for the identification of abuse of such substances in bovine production in the EU.

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Annex A. Analytical methods: performance characteristics and validation

1. Method performance

Commission Decision 2002/657/EC specifies the performance characteristics and interpretation of results for analytical methods used to implement the residue monitoring required by Council Directive 96/23/EC. According to this decision, suitable screening methods are those for which it can be demonstrated in a documented traceable manner that they are validated and have a false compliant rate of <5 % at the level of interest. In the case of confirmatory methods, distinction is made between those methods suitable for confirming the presence of prohibited (group A) substances and those that may be used for confirming the presence of licensed veterinary drugs and contaminants (group B substances). For group A substances, LC (liquid chromatography) or GC (gas chromatography) separation with MS (mass spectrometry) or IR (infrared) spectrometric detection is required and, in the case of MS techniques where mass fragments are produced, the relationship between different classes of mass fragment and identification points are specified, with a minimum of 4 identification points being required for confirmation. Apart from LC or GC chromatographic separation with MS or IR spectrometric detection, suitable confirmatory techniques for group B substances may include LC with diode-array or fluorescence detection for appropriate molecules, two-dimensional thin layer chromatography (2-D TLC) with full-scan UV/VIS detection, and GC with electron capture detector (GC-ECD), LC-immunogram or LC-UV/VIS where at least two different chromatographic separations are used.

Commission Decision 2002/657/EC specifies the performance criteria for methods, including recovery and accuracy, trueness and precision. The Decision specifies, also, the validation required to demonstrate that each analytical method is fit for purpose. In the case of screening methods, validation requires determination of the performance characteristics of detection limit (CCβ), precision, selectivity/specificity and applicability/ruggedness/stability. For confirmatory methods, in addition to determination of those performance characteristics, validation requires, also, determination of decision limit (CCα) and trueness/recovery.

The analytical requirements for the determination of dioxins, dioxin-like and non dioxin-like PCBs are laid down in Commission Regulation (EC) No 252/2012[49]. Following a criteria approach analyses can be performed with any appropriate method, provided the analytical performance criteria are fulfilled. While methods, such as GC-MS, cell-and kit-based bioassays are allowed for screening purposes, the application of GC/high resolution MS is mandatory for confirmation of positive results.

2. Screening methods

Screening methods include a broad range of methods, such as enzyme-linked immunosorbent assays (ELISA), biosensor methods, receptor assays, bioassays and biomarkers for the presence of residues of concern. These screening methods generally use specific binding of the molecular structure of the residue(s) by antibodies or other receptors to isolate and measure the presence of the residues in biological fluids (urine, plasma) or sample extracts. More recently, biomarkers for the use of prohibited substances such as hormonal growth promoters have been identified as potential screening methods for these substances. Physico-chemical methods, such as LC or GC with various detectors, may be used, also, as screening methods.

In the particular case of antimicrobials, microbiological or inhibitory substance tests are widely used for screening. In such tests, using multiple plates/organisms or kit formats, the sample or sample extract is tested for inhibition of bacterial growth. If, after a specific period of incubation, the sample inhibits the growth of the bacteria, it is considered that an antibacterial substance is present in the

[49] Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006. OJ L 84, 23.3.2012, pp. 1–22.

sample, but the specific substance is not identified. Given that this is a qualitative analytical method, a misinterpretation of the results cannot be ruled out, and some false positives can occur. Microbiological methods are screening methods which allow a high sample throughput but limited information is obtained about the substance identification and its concentration in the sample. When residues are found in a screening test, a confirmatory test may be carried out, which normally involves a more sophisticated testing method providing full or complementary information enabling the substance to be identified precisely and confirming that the MRL has been exceeded.

3. Confirmatory methods

With the significant developments in liquid chromatography and in mass spectrometry over the last decade, confirmatory methods are largely MS-based, using triple quadrupole, ion trap, and other MS techniques. Indeed, with current methodology in a modern residue laboratory with good MS capability, much of the two-step approach of screening followed by confirmatory testing has been replaced by single confirmatory testing. This has been made possible by the greatly-enhanced separation capability of ultra high performance liquid chromatography (UPLC), coupled with sophisticated MS detection systems. The parallel growth in more efficient sample extraction/clean-up methods is an integral part of these advances in confirmatory methods and such chemistries produce rapid, sometimes (semi)-automated procedures providing multi-residue capability. Techniques based on highly-efficient sorbent chemistries for solid-phase extraction (SPE) and techniques such as QuEChERS (quick, easy, cheap, effective, rugged, safe) are examples of these advances. Such combination of UPLC-MS/MS methods with appropriate sample extraction/cleanup technologies allows for unequivocal, quantitative determination of a broad spectrum of substances in a single analytical method.

Particularly in the area of prohibited substances, the power of MS techniques is being applied to identify hitherto unknown compounds and to identify exogenous from endogenous substances. For example, time-of-flight (TOF) MS provides accurate mass capability and may allow for retrospective analysis capability from the MS data. The technique of GC–combustion–isotope ratio MS has been utilized to study the $^{13}C/^{12}C$ ratio of substances in urine samples, where, for example, such $^{13}C/^{12}C$ ratio differs significantly between endogenous (or natural) testosterone and exogenous (or synthetic) testosterone.

ABBREVIATIONS

ADI	acceptable daily intake
AFSSA	Agence Française de Sécurité Sanitaire des Aliments/French Food Safety Agency
BIOHAZ Panel	EFSA Panel on Biological Hazards
BIOMO	Biological Monitoring
BMD	benchmark dose
$BMDL_{10}$	lower 95 % confidence limits for a benchmark response of 10 %
b.w.	body weight
CCα	decision limit
CCβ	detection limit
CONTAM Panel	EFSA Panel on Contaminants in the Food Chain
CVMP	Committee for Medicinal Products for Veterinary Use
CVO	Chief Veterinary Officer
DCM	Dietary & Chemical Monitoring
DDT	dichlorodiphenyltrichloroethane
DL-PCB	dioxin-like polychlorinated biphenyl
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
ELISA	enzyme-linked immunosorbent assay
EMA	European Medicines Agency
EU	European Union
FCI	food chain information
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GFP	good farming practice
GHP	good hygiene practice
HBCDD	hexabromocyclododecane
HCH	hexachlorocyclohexane
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IR	infrared
LC	liquid chromatography
MBI	mercaptobenzimidazole
ML	maximum level
MOE	margin of exposure

MRL	maximum residue limit
MRPL	minimum required performance limit
MS	Member State/mass spectrometry
NC	non-compliant
NDL-PCB	non dioxin-like polychlorinated biphenyl
NOAEL	No-observed-adverse-effect level
NRCP	national residue control plan
NSAID	non-steroidal anti-inflammatory drug
OIE	World Organization for Animal Health
PBDE	polybrominated diphenylether
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofuran
PFC	perfluorinated compound
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonate
PSM	plant secondary metabolites
QAS	quality assurance schemes
QuEChERS	quick easy cheap effective rugged safe
RAL	resorcylic acid lactone
SAS	Scientific Assessment Support
SCF	Scientific Committee on Food
SCVPH	Scientific Committee on Veterinary measures relating to Public Health
SEM	semicarbazide
SPE	solid-phase extraction
T3	triiodothyronine
T4	thyroxine
TDI	tolerable daily intake
TEQ	toxic equivalent
TOF	time-of-flight
TOR	terms of reference
TWI	tolerable weekly intake
UPLC	ultra-high-performance liquid chromatography
VMP	veterinary medicinal product
WHO	World Health Organization

Appendix C: Assessment on animal health and welfare

SUMMARY

Meat inspection, comprising both *ante-mortem* and *post-mortem* inspection, is recognised as a valuable tool for surveillance and monitoring of animal diseases and welfare conditions, and helps in the recognition of outbreaks of existing or new disorders or disease syndromes, in situations where clinical signs are not detected on-farm. Meat inspection represents a practical way to evaluate the welfare of bovines on-farm, and is the only way to evaluate the welfare of bovines during transport and associated handling. Changes in the meat inspection system may negatively affect surveillance and monitoring effectiveness of animal diseases and welfare conditions. The focus of the AHAW Panel was to assess the implications for surveillance of animal health and welfare of the changes proposed to the current meat inspection system by the Biological Hazards (BIOHAZ) and Contaminants in the Food Chain (CONTAM) Panels. Briefly, the recommendations of the BIOHAZ Panel were related to (i) shorter transport and lairaging; (ii) focusing and expanding food chain information to enable related risk categorisation of both farms/herds and slaughterhouses; (iii) omission of palpation and incision in animals subjected to routine slaughter at *post-mortem* inspection (if necessary, detailed inspection with potential use of palpation and incision should be carried out separately); and (iv) additional control measures of high-risk herds (as logistic slaughter, reduced line speed slaughter, decontamination interventions, etc.). The CONTAM Panel recommendations included (i) the ranking system of chemical substances and its updating; (ii) development of risk-based strategies for sampling, including new hazards identified; and (iii) improvement of analytical techniques.

To assess the impact of proposed changes to the current meat inspection on the overall sensitivity for surveillance and control of animal diseases and welfare conditions, the results and conclusions of a quantitative assessment, carried out by an external consortium (COMISURV) under an EFSA procurement, were analysed. This report assessed the impact of a change from the current bovine meat inspection to a visual-only system in terms of detection efficiency of a list of seventeen selected diseases and welfare conditions of cattle. Additional information from the scientific literature and other recent assessments were also taken into account by experts to assess the impact of proposed changes on the detection probability and overall surveillance of animal diseases and welfare conditions. Finally, modelling was applied to assess the impact of reduced meat inspection sensitivity of the visual only system on the area surveillance of bovine tuberculosis on Officially Tuberculosis Free (OTF) countries and zones.

The difference in detection fraction between the current and the visual only systems was significant (non-overlapping 90 % probability intervals) for granuloma/bovine tuberculosis and *Taenia saginata* cysticercosis. A significant reduction (based on non-overlapping 90 % probability intervals) in the probability of detection at meat inspection for respiratory diseases, cysticercosis, fasciolosis (primarily for mild cases) and bovine tuberculosis was also noted.

In the case of the exotic diseases, there was little difference in component sensitivity between the current and visual-only systems for any of the diseases considered. For bovine tuberculosis, a shift to a visual only meat inspection would substantially reduce surveillance quality, with an estimated fivefold reduction in sensitivity. Animal welfare conditions were not affected by the change to visual only, as most of the conditions can be detected during effective *ante-mortem* inspection.

Although it is recognised that *Mycobacterim bovis* is not transmitted to humans through consumption of meat and meat products, it is also true that slaughterhouse meat inspection is of great relevance for the surveillance of *Mycobacterium bovis* infection in herds and animals. In non-OTF countries and regions, meat inspection at the slaughterhouse is a complement to regular and *ad hoc* bTB testing of animals and herds for the control and eradication of the disease, and accounts for a significant proportion of new breakdowns discovered. In OTF countries and regions, continuous monitoring is

required by legislation to substantiate the OTF status, and meat inspection may be the only surveillance component in place. It was concluded that *post-mortem* inspection is an important component of the overall bovine tuberculosis surveillance in both OTF and non-OTF Member States and zones thereof, and a reduction in the sensitivity of this component may substantially reduce surveillance quality. This effect may have the greatest impact in bovine tuberculosis surveillance in OTF Member States and zones thereof, which relies almost exclusively on surveillance by meat inspection.

A qualitative risk assessment by the UK Food Standards Agency concluded that a change to a visual only inspection system would reduce the number of bovine tuberculosis cases found at the slaughterhouse using *post-mortem* inspection. The negative impact that this reduction would have on the overall surveillance and control of bovine tuberculosis was not quantitatively determined, but it was estimated to be greater in OTF Member States than in non-OTF Member States.

Overall, the conclusions of this opinion regarding bovine tuberculosis are consistent with previous EFSA opinions showing a negative impact on tuberculosis detection if palpation and incision of relevant organs (lung, respiratory tract lymph nodes) were to be removed from inspection tasks. To avoid decreasing the overall sensitivity of surveillance, the experts concluded that these inspection tasks, aimed at the detection of bovine tuberculosis, should be retained in the meat inspection system.

A quantitative model was implemented for assessing the impact of different meat inspection options on the overall sensitivity of a bTB surveillance system in OTF countries. It was shown that a reduction in the sensitivity of the bTB detection test at individual (animal) level (due to the change to a visual only meat inspection) would have a negative impact on the surveillance system sensitivity. This reduction in the sensitivity of meat inspection arising from a change to a visual-only system would affect the area sensitivity in such a way that several EU Member States would not achieve a 95 % probability of detecting at least one positive herd when the true prevalence is above the threshold and would be unable to state with 95 % confidence that the true prevalence of positive herds is below the threshold (i.e. 0.001) given that all slaughtered animals tested negative during meat inspection.

Bovine cysticercosis (caused by the larval stage of the human parasite *Taenia saginata*) causes lesions in striated muscle and to a lesser extent in other organs. Surveillance data of bovine cysticercosis are nowadays provided only through meat inspection at the slaughterhouse. The sensitivity of the current meat inspection system for detection of bovine cysticercosis is considered to be low, and there would be a further significant decrease in effectiveness of detection if moving from the current to a visual only system, with a fourfold reduction in the detection fraction. The probable consequences of this reduction would be an increase in the likelihood of transmission of *Taenia saginata* and, in turn, an increase in prevalence of the infection in bovines. The experts concluded that if a visual only meat inspection system were to be adopted, alternative procedures should then be applied that provide equivalent or even increased capability of detection than, that of current meat inspection.

Fasciolosis prevalence is underestimated by clinical surveillance, and the present *post-mortem* meat inspection procedure is the most effective tool in routine liver fluke surveillance in cattle. A less sensitive, visual only, inspection of the liver would result in a reduction in detection rate for liver fluke in individual bovine animals. However, given the current prevalence of *Fasciola* in cattle, it is unlikely that the reduction in animal-level sensitivity would significantly impact herd-level sensitivity (as it is unlikely that all infected cattle within a herd would be missed). Feedback to farmers of *Fasciola hepatica* detected at meat inspection is low at present and the real risk to animal health/welfare from this disease, caused by a change to a visual only meat inspection method is probably low. An improvement in this feedback of information is recommended.

For respiratory diseases, the palpation and incision of the lungs and related tissues, as defined by legislation, improves the sensitivity of detecting respiratory lesions. However, it was concluded by the

experts that the risk to animal health/welfare for respiratory diseases caused by a change to a visual only meat inspection method is probably low.

Animal based welfare indicators have been developed for the on-farm assessment of welfare, and specifically of lameness in bovines (dairy cows), and they could be adapted for use during routine *ante-mortem* inspection in slaughterhouses. Food chain information should include animal welfare status in order to complement the slaughterhouse surveillance systems (*ante-mortem* and *post-mortem* inspection) and the latter could be used to identify on-farm welfare status.

Other recommendations on biological or chemical hazards would not have a negative impact of surveillance of animal diseases and welfare conditions.

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1. Introduction

In this mandate, the AHAW Panel and the *ad hoc* working group (WG) are focusing on the implications for animal health and welfare of any changes to the current meat inspection (MI) system, as proposed by Biological Hazards (BIOHAZ) and Contaminants in the Food Chain (CONTAM) Panels. 'Implications for animal health and welfare' relates specifically to monitoring and surveillance of animal disease and welfare conditions during MI (that is, inspection at the slaughterhouse before and after slaughter, in this document referred to as *ante-mortem* (AMI) and *post-mortem* inspection (PMI), respectively). Therefore, the objective of this work is to identify possible effects and to assess the possible consequences on surveillance and monitoring of animal health and welfare conditions if the proposed changes on MI system were applied.

Apart from its contribution to assuring public health, current MI also contributes to surveillance and monitoring of animal diseases and welfare conditions (EFSA, 2003), and may be an important component of the overall monitoring and surveillance system. Further, MI offers the only opportunity for surveillance of some diseases and welfare conditions at certain stages of a control and eradication program. Therefore, any change in MI system that could lead to a loss of sensitivity (reduced probability of detection) may compromise the surveillance efficacy.

In the case of animal welfare, AMI and PMI also play a role in surveillance and monitoring welfare of farmed animals, and moreover, it is the only place to assess poor welfare during transport of animals to the slaughterhouse. Bovine animals are subjected to different periods of feed and water restriction, handling and transport prior to arrival at a slaughterhouse. AMI begins with the observation of animals at the time of unloading from the transport vehicle and the purpose is to determine whether animal welfare has been compromised in any way on the farm and during handling and transport. Welfare conditions such as fitness to travel, prevalence of injury, lameness and exhaustion, and cleanliness of animals are ascertained during AMI. Certain other welfare conditions such as bruising may not always be detectable during AMI, but become visible during routine PMI. Welfare conditions related to foot and leg disorders would be detectable only if the animals are observed during walking, e.g. unloading or moving to lairage pens, and are also less likely to be detected by visual examination during PMI. When MI detects apparent defects or abnormalities, incision of the relevant joints, tendons and/or muscles could be necessary to determine the presence, as well as severity, of foot and leg disorders.

2. Implications for surveillance and monitoring for bovine health and welfare of changes to meat inspection as proposed by the BIOHAZ Panel

2.1. The proposed BIOHAZ changes

The proposed modifications for the MI system that may have implications for animal health and welfare (see BIOHAZ Appendix A for full details), are summarised below:

- Shorter transport and lairaging (may be beneficial in terms of reducing cross-contamination of *Salmonella* spp. and pathogenic VTEC) (see BIOHAZ Appendix A, Section 4).

- Food chain information (FCI) should be expanded and more focused on priority biological hazards, so to enable related risk categorisation of both farms/herds and slaughterhouses including through use of Harmonised Epidemiological Indicators (HEIs), as well as selecting optimal risk control options related to slaughter and processing of higher-risk batches at abattoirs (see BIOHAZ Appendix A, Section 5.1).

- High-risk herds should be subjected to additional control measures such as logistic slaughter, reduced line speed slaughter, decontamination interventions or being directed to abattoirs which have demonstrated an enhanced ability to control carcasses contamination (see BIOHAZ Appendix A, Section 4).

- Omission of palpation and incision in animals subjected to routine slaughter at PMI (if abnormalities are detected during visual inspection or reported in food chain information, then detailed inspection (with potential use of palpation and incision) should be carried out separately from the routine inspection of carcasses in order to prevent cross-contamination) (see BIOHAZ Appendix A, Section 5.3).

2.2. Quantitative assessment of the impact of changes on meat inspection on the effectiveness of the detection of animal diseases and welfare conditions (COMISURV report)

To assess the impact of proposed changes to the current MI on the overall sensitivity for surveillance and control of animal diseases and welfare conditions, a quantitative assessment was performed based on expert opinion and modelling. An external consortium (COMISURV), under the provision of an EFSA procurement, performed this work.

2.2.1. Materials and methods

The detailed methodology, as well as results and conclusions, together with assumptions and limitations of the modelling, can be found in the COMISURV report for bovine MI (Dupuy et al., 2012).

- These limitations include:

- The parameters for the probability of detection were based on expert opinion and therefore there is uncertainty as to the true range of these values.

- Limited number of experts to cover the different subjects needed for the assessment.

- Variations in the epidemiological situation of the disease and welfare conditions between countries.

A brief description of the methodology that was applied in the COMISURV report is given below.

2.2.1.1. Identification of diseases and conditions which could be affected by changes in meat inspection

An initial long list of bovine diseases and welfare conditions relevant to the EU was established, based on general textbooks, references, and expert opinion. WG experts filtered this list using a decision tree, following previous methodology and criteria developed for previous opinions (EFSA BIOHAZ, CONTAM and AHAW Panels 2011, 2012a). A disease or condition was retained on the list by the WG experts using the following criteria:

- A high likelihood of detection of a disease or welfare condition at MI, at the age that animals are presented at the slaughterhouse (if likelihood was medium, low, or the condition was undetectable, it was excluded from the list).

- The disease or welfare condition is considered relevant to the EU (conditions not occurring in EU Member States (MSs) were omitted).

- The condition is relevant to animal health and welfare (conditions mainly relevant to public health were not retained, as they should be dealt with by the BIOHAZ Panel).

- The slaughterhouse surveillance component (AMI + PMI) provided by MI is significant for the overall surveillance of the disease or welfare condition (if there are other surveillance or detection systems much more effective and highly preferable to MI, the conditions were removed from the list).

The final list of conditions established by the WG experts to be assessed by the COMISURV consortium is shown in Table 1. A total of seventeen conditions (ten diseases and seven welfare conditions) were included in this list.

2.2.1.2. Development of a stochastic model to quantify the effectiveness of meat inspection

A stochastic model to quantify the monitoring and surveillance effectiveness of MI in bovines was developed. A definition of a typical and a mild case for each of the diseases and welfare conditions listed in Table 1 was provided by the COMISURV experts.

Typical cases were by definition detectable cases and express more developed clinical signs than mild cases. Typical cases were defined as those in which clinical signs and/or lesions were expected to be observed in more than 60 % of affected or infected animals arriving at slaughter.

A mild case of a disease or welfare condition is the form that can be seen in the early stages of the disease or at some point between the subclinical (and without pathological lesions that are observable through the meat inspection process) and the fully developed form (i.e. 'typical' form). A mild case is neither typical nor non-detectable. The animal will probably present more subtle signs than in the typical case. As an example, a typical case of hydatidosis is assumed to present a limited number of cysts of different size, which contain a clear fluid under pressure, in liver and/or lungs. A mild case of echinococcosis is assumed to present itself at PMI with one small cyst in the liver or lungs that contains a clear fluid under pressure. The proportion of affected animals presenting as typical or mild cases, as well as the non-detectable fraction, was estimated (see COMISURV report for details).

The most likely detection probability, as well as 5th and 95th percentiles (the probability intervals) of the output distribution of AMI, PMI, and AMI and PMI combined were derived for each of the conditions in Table 1 both prior to and following suggested changes to the MI system as proposed by BIOHAZ. The inspection protocols in the current and visual only systems are compared in Table 2.

Probabilities of detection were estimated as was surveillance performance (referred to as Stage 2 in the COMISURV report). For endemic diseases and welfare conditions, the performance of surveillance for case-finding was measured as the detection fraction (the proportion of cases in the population that are detected by the MI surveillance). For exotic diseases, the focus was placed on early detection and component sensitivity (probability that a surveillance system will detect at least one case, given that the disease is present in the population at a specific prevalence).

Table 1: List of infectious diseases and welfare conditions in bovines identified by the AHAW WG for consideration in the assessment conducted by COMISURV

	List of diseases and welfare conditions	Stage 2[1]	Stage 3[2]
Diseases	Echinococcosis/hydatidosis	X	
	Enzootic bovine leukosis	X	
	Fasciolosis	X	X
	Granuloma (tuberculosis, lymph nodes lesions for actinobacillosis or tumours)	X	X
	Necrobacillosis	X	
	Pathological lesions in the heart of possible bacterial origin	X	
	Respiratory diseases (transport fever and other causes of pneumonia and associated pleuritis)	X	
	Cysticercosis (*Taenia saginata*)	X	
	Ulcerative diseases (malignant catarrhal fever and bluetongue)	X	X
	Vesicular diseases (foot and mouth disease and vesicular stomatitis)	X	X
Welfare issues	Bruising and injury	X	
	Cleanliness score	X	
	DFD meat	X	
	Foot and leg disorders (foot and leg disorders linked to trouble in housing system but excluding fractured limbs)	X	X
	Fractured limb	X	
	Integument alterations	X	
	Low body condition	X	

1Stage 2 - all diseases and welfare conditions listed were evaluated with regards to their probability of being detected at MI.
2Stage 3 - for selected diseases and welfare conditions, surveillance by MI was compared with other surveillance components, i.e., clinical surveillance, serological survey or control programme.
DFD - Dark, Firm and Dry.

Table 2: List of AMI and PMI procedures for bovines under and over six weeks old according to Regulation (EC) 854/2004 (the current procedure) and according to the proposed changes in procedures based on visual inspection (visual only), where V represents visual inspection; I represents incision; P represents palpation. Grey boxes indicate inspection points where the visual only scenario implies a change to current procedures for bovine under and/or over six weeks old.

Inspection step			**Inspection procedure**			
			Current		**Visual only**	
			Bovine <6 weeks	**Bovine >6 weeks**	**Bovine <6 weeks**	**Bovine >6 weeks**
AMI	Food chain information	Diseases, morbidity and mortality on-farm	V	V	V	V
	Live animal	General health	V	V	V	V
PMI	Whole carcass	External surface	V	V	V	V
	Head	Head and throat	V	V	V	V
		Retropharyngeal lymph nodes	I	I	V	V
		Submaxillary and parotid lymph nodes	–	I	–	V
		External and internal masseter	–	V + I	–	V
		Mouth and fauces	V	V	V	V
		Tongue	P	P	V	V
	Lungs	Parenchyma	V + P + I[1]	V + P +I[1]	V	V
		Trachea	V + I[1]	V + I[1]	V	V
		Major bronchi	I[1]	I[1]	V	V
		Mediastinal lymph nodes	I	I	V	V
		Bronchial lymph nodes	I	I	V	V
	Oesophagus		V	V	V	V
	Heart	Heart	V + I	V + I	V	V
		Pericardium	V	V	V	V
	Diaphragm		V	V	V	V
	Liver	Parenchyma	V + P + I[2]	V+ P + I	V	V
		Hepatic lymph nodes (=portal)	V + P + I[2]	V + P	V	V
		Pancreatic lymph nodes	V + I[2]	V + P	V	V
	GI tract	Stomach and intestines	V	V	V	V
		Mesentery	V	V	V	V
		Gastric lymph nodes	V + P+ I[2]	V + P+ I[2]	V	V
		Mesenteric lymph nodes	V + P + I[2]	V + P +I[2]	V	V
	Spleen		V + P[3]	V + P[3]	V	V
	Kidneys	Parenchyma	V + I[2]	V + I[2]	V	V
		Renal lymph nodes	V + I[2]	V+ I[2]	V	V
	Uterus and mammary glands	Uterus	–	V	–	V
		Udder	–	V + P[3]+I[1]	–	V

Inspection step		Inspection procedure			
		Current		Visual only	
		Bovine <6 weeks	Bovine >6 weeks	Bovine <6 weeks	Bovine >6 weeks
	Supramammary lymph nodes	–	V+ P[3]+ I[2]	–	V
Pleura		V	V	V	V
Peritoneum		V	V	V	V
Umbilical area		V + P + I[4]	–	V	–
Joints		V + P + I[4]	–	V	–
Synovial fluid		V	–	V	–

[1]Not required if not intended for human consumption.
[2]Incision if necessary.
[3]Palpation if necessary.
[4]Incision if in doubt.

Additionally, for four of the selected diseases and one welfare condition, considered to be more adversely affected in terms of detection probability following the proposed changes to the MI system, further modelling was implemented to quantify the effectiveness of monitoring and surveillance (detection probability, component specific and overall detection fraction/component sensitivity) in the overall monitoring and surveillance system, both prior to and following suggested changes to the meat inspection system (referred to as Stage 3 in the COMISURV report).

Note that the word surveillance as used in this opinion does not imply that any action is taken to capture, or act upon, the information that is collected. It merely points to the potential of these systems to be used for such purposes.

2.2.2. Results and discussion

The detection fraction and the probability of detection for endemic diseases using the current MI system and the visual only system are shown in Table 3 and in Annex 1 (Tables A to D), respectively. The estimated component sensitivities of slaughterhouse surveillance for diseases classified as exotic are presented in Table 4 (referred to as Stage 2 in COMISURV report).

For the endemic diseases analysed, the difference in detection fraction between the current MI system and the visual only system was significant (non-overlapping 90 % probability intervals) for granuloma/bovine tuberculosis (bTB) (with an 81 % reduction in detection fraction) and *Taenia saginata* cysticercosis (76 %) (Table 3).

A significant reduction (based on non-overlapping 90 % probability intervals) in the probability of detection at meat inspection of respiratory diseases, cysticercosis, fasciolosis (primarily for mild cases) and bTB was also noted (based on non-overlapping 90 % probability intervals) (see Annex 1, Tables A to D).

Expert elicitation in Stage 2 indicated that typical and mild cases of all seven animal welfare conditions are detectable. The detection fraction for animal welfare conditions (Table 3) under the current MI system and the proposed visual only system are very similar.

Table 3: Overall proportion of infected or affected animals successfully detected (**detection fraction**, presented as mode, 5th and 95th percentiles) as having fourteen endemic diseases and welfare conditions selected for the assessment of the case-finding capacity of slaughterhouse surveillance, under the current system (in line with European legislation) and with a system based on meat inspection by visual examination only. The input required to estimate the parameters was derived through elicitation of expert opinion and from the literature, using the French situation as an example.

	Disease/welfare condition	Detection fraction					
		Current			Visual only		
		5 %	**Mode**	95 %	5 %	**Mode**	95 %
Infectious diseases	*Echinococcus*/hydatidosis	0.093	**0.112**	0.131	0.062	**0.078**	0.094
	Fasciolosis	0.099	**0.126**	0.151	0.073	**0.094**	0.114
	Granuloma/bovine tuberculosis	0.032	**0.052**	0.083	0.005	**0.010**	0.017
	Necrobacillosis	0.16	**0.23**	0.33	0.14	**0.21**	0.31
	Pathological lesions in the heart	0.15	**0.18**	0.23	0.15	**0.18**	0.23
	Respiratory diseases	0.13	**0.23**	0.33	0.10	**0.19**	0.27
	Taenia saginata/Cysticercus bovis	0.074	**0.115**	0.171	0.015	**0.028**	0.045
Welfare conditions	Bruising and injury-related haemorrhage[1]	0.54	**0.60**	0.67	0.54	**0.60**	0.67
	Cleanliness score	0.21	**0.25**	0.29	0.21	**0.25**	0.29
	DFD meat[1]	0.15	**0.22**	0.29	0.16	**0.24**	0.31
	Foot and leg disorders	0.14	**0.15**	0.17	0.14	**0.15**	0.17
	Fractured limb[1]	0.99	**0.99**	1.00	0.99	**0.99**	1.00
	Integument alterations	0.074	**0.096**	0.124	0.074	**0.096**	0.124
	Low body condition score	0.20	**0.23**	0.28	0.20	**0.23**	0.28

[1]Relates to transport-afflicted welfare conditions and the population considered is therefore animals transported to slaughterhouses.
Shaded rows indicate diseases identified as having significant differences in detection fraction in the visual only scenario.
DFD - Dark, Firm and Dry.

For the exotic diseases, there is little difference in component sensitivity between the current and visual only systems for any of the diseases considered (Table 4).

Table 4: Probability of detecting one or more animals as infected at meat inspection during a one-month period (**component sensitivity**, presented as mode, 5th and 95th percentiles) for three infectious diseases regarded as being **exotic**. The design prevalences used in the estimations are also given.

Disease	Component sensitivity						Design prevalence	
	Current			Visual only			Herd	Within-herd
	5 %	**Mode**	95 %	5 %	**Mode**	95 %		
Enzootic bovine leukosis	0.061	**0.144**	0.262	0.056	**0.132**	0.242	0.002	0.01
Ulcerative diseases[1]	0.997	**0.999**	1.000	0.996	**0.999**	1.000	0.002	0.1
Vesicular diseases[1]	0.999	**0.999**	1.000	0.999	**0.999**	1.000	0.002	0.1

[1]See Table 1 for the list of diseases.

The possible influences of risk categorisation according to a hypothetical human health risk on the overall probability of detection of animal health and welfare conditions were also assessed in the COMISURV report. There was no predefined public health risk (PHR) (for example, prevalence of *Salmonella*-infected animals in the herd) and, therefore, the influence of or co-variation with any farm-level risk factor could not be taken into account in the analysis. Instead, three different scenarios were considered in the model, depending on the distribution of animals with a higher or lower risk of being affected by the condition under consideration in the different PHR categories (low-risk, high-risk). In the neutral scenario, equal proportions of animals coming from high- and low-risk herds are

found in the high PHR stratum (0.20 for both); in the counteract scenario, the high PHR stratum consists of a lower proportion of animals coming from high-risk herds compared to low-risk herds (0.20 vs. 0.80); and in the synergy scenario the high PHR stratum consists of a higher proportion of animals coming from high- risk herds (0.80 vs. 0.20). The results are shown in Table 5.

It can be noted that, for most diseases, the system is marginally affected even when the PHR counteracts the animal health risk. This mainly reflects the fact that visual only inspection and current MI are considered to perform equally well for several of the diseases and welfare conditions considered.

Table 5: Effect of three risk categorisation scenarios on the mode of **detection fraction** and **component sensitivity** in models describing slaughterhouse surveillance for endemic and exotic diseases, respectively. Seventeen diseases and welfare conditions were considered. These estimates take into account the relative proportions of typical, mild and subclinical cases, as well as their probabilities of detection. For comparison, the corresponding estimates for the current inspection system are given (also presented in Tables 3 and 4).

	Disease or welfare condition	**Risk categorisation under visual only**			***Current***
		Equal proportions[1]	**High proportion in low-risk[2]**	**High proportion in high risk[3]**	
Infectious diseases	*Echinococcus*/hydatidosis	0.09	0.09	0.10	*0.11*
	Enzootic bovine leukosis	0.15	0.14	0.14	*0.14*
	Fasciolosis	0.10	0.10	0.12	*0.13*
	Granuloma/bovine tuberculosis	0.01	0.01	0.02	*0.05*
	Necrobacillosis	0.22	0.22	0.23	*0.23*
	Pathological lesions in the heart	0.16	0.16	0.18	*0.18*
	Respiratory diseases	0.21	0.21	0.23	*0.23*
	Taenia saginata/Cysticercus bovis	0.05	0.05	0.10	*0.12*
	Ulcerative diseases	1.00	0.95	1.00	*1.00*
	Vesicular diseases	1.00	1.00	1.00	*1.00*
Welfare conditions	Bruising and injury-related haemorrhage	0.60	0.60	0.60	*0.60*
	Cleanliness score	0.25	0.25	0.25	*0.25*
	DFD meat	0.23	0.23	0.22	*0.22*
	Foot and leg disorders	0.15	0.15	0.15	*0.15*
	Fractured limb	0.99	0.99	1.00	*0.99*
	Integument alterations	0.09	0.09	0.09	*0.10*
	Low body condition score	0.22	0.22	0.22	*0.23*

[1]Equal category branch proportions for animals belonging to high- and low-risk groups with regards to an overarching farm level risk factor (the proportion of animals belonging to a high PHR category is 0.2 for both groups).

[2]Different category branch proportions for animals belonging to high and low risk groups with regards to an overarching farm level risk factor (the proportion of animals belonging to a high PHR category is 0.8 for the low risk group and 0.2 for the high risk group).

[3] Different category branch proportions for animals belonging to high- and low-risk groups with regards to an overarching farm-level risk factor (the proportion of animals belonging to a high PHR category is 0.2 for the low-risk group and 0.8 for the high-risk group).

DFD - Dark, Firm and Dry.

Four infectious diseases (foot and mouth disease, bluetongue, bTB and fasciolosis) and one welfare condition (foot and leg disorder) were modelled to assess the impact of MI changes on the overall sensitivity of detection of the conditions, referred to as Stage 3 in COMISURV report. For two of these (foot-and-mouth disease, bluetongue), component sensitivity was the outcome measure for

comparison between surveillance components, and for the remaining three, detection fraction was used. The results are shown in Tables 6 and 7.

When the overall sensitivity of the surveillance was assessed, a shift to visual-only meat inspection would have an impact for fasciolosis and bTB. For fasciolosis, the quality of the surveillance system would be significantly reduced (from 0.126 to 0.094). For bTB, meat inspection and a field-based control programme are each important parts of the overall surveillance. Case detection (the proportion of cases in the population that are detected by the surveillance) of the in-farm control programme is higher than that for meat inspection. A shift to a visual only meat inspection would substantially reduce surveillance quality (decrease of sensitivity from 0.052 to 0.010) (Table 6).

The capacity of slaughterhouse and clinical surveillance systems in the detection of foot and leg disorders was ascertained in Stage 3 (Table 6). For foot and leg disorders, a shift from the present system to visual only meat inspection would not affect detection quality (detection fractions of 0.15).

Table 6: Case-finding capacity of slaughterhouse surveillance and of other surveillance components, measured by **detection fraction** (presented as mode, 5th and 95th percentiles), for the endemic diseases fasciolosis and bTB and the welfare condition foot and leg disorders.

Disease or welfare condition	MI						Clinical surveillance			Control programme		
	Current			Visual only								
	5 %	**Mode**	95 %	5 %	**Mode**	95 %	5 %	**Mode**	95 %	5 %	**Mode**	95 %
Fasciolosis	0.099	**0.126**	0.151	0.073	**0.094**	0.114	0.00	**0.00**	0.00	NA	**NA**	NA
Granuloma / bTB	0.032	**0.052**	0.083	0.005	**0.010**	0.017	0.00	**0.00**	0.00	0.63	**0.68**	0.74
Foot and leg disorders	0.14	**0.15**	0.17	0.14	**0.15**	0.17	0.01	**0.02**	0.03	NA	**NA**	NA

NA, not applicable.

For the epizootic diseases, the sensitivity of each surveillance component (including visual only MI) is very high, and the probability that the surveillance system detects at least one case is similar for each of the surveillance methods (Table 7).

Table 7: **Sensitivity** of the slaughterhouse surveillance component (presented as mode, 5th and 95th percentiles), and for clinical surveillance, with regards to detection of foot and mouth disease and bluetongue.

Disease	MI						Clinical surveillance		
	Current			Visual only					
	5 %	**Mode**	95 %	5 %	**Mode**	95 %	5 %	**Mode**	95 %
Vesicular diseases	0.999	**0.999**	1.000	0.999	**0.999**	1.000	1.000	**1.000**	1.000
Ulcerative diseases	0.997	**0.999**	1.000	0.996	**0.999**	1.000	1.000	**1.000**	1.000

2.3. Qualitative assessment of the role of meat inspection in surveillance programmes on selected diseases and welfare conditions

The qualitative assessment involved literature review and expert opinion from the WG members, for the diseases identified as having a significant reduction in the probability of detection and/or in the fraction detected in the quantitative assessment of the COMISURV report (bTB, fasciolosis, *T. saginata* cysticercosis and respiratory diseases) and welfare conditions.

2.3.1. Bovine tuberculosis

2.3.1.1. Description of the disease and prevalence and relevance in EU

Bovine tuberculosis (bTB) is an infectious disease of cattle caused by *Mycobacterium bovis and M. caprae*[50] and one of the biggest challenges facing the cattle farming industry in some EU MSs. *M. bovis* is also capable of infecting a wide range of warm-blooded animals, including domestic goats and sheep and humans. A number of wildlife animal species, such as deer, wild boars, badgers and the European bison, may contribute to the spread and/or maintenance of *M. bovis* infection in cattle. Infected humans have also transmitted the infection to bovines (Schiller et al., 2011).

The main transmission routes of *M. bovis* to humans are through contaminated food (especially raw milk and raw milk products) or through direct contact with infected animals (occupational hazard). The risk of transmission of *M. bovis* to humans by meat consumption has been reviewed elsewhere in this opinion (see BIOHAZ Appendix A, Section 5.4.2, for details), and is currently considered negligible owing to the non-meat-borne nature of the agent. The role of slaughterhouse MI in bovine TB surveillance is, however, of great relevance for the surveillance programmes of the infection in herds and animals.

According to the most recent Zoonoses Report (EFSA and ECDC, 2013), 15 MSs (Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Latvia, Luxembourg, the Netherlands, Poland, Slovakia, Slovenia and Sweden) as well as Norway and Switzerland, were Officially Tuberculosis Free (OTF) in 2011 according to EU legislation, while in some MSs, such as Italy and the United Kingdom, parts of the country are classified as OTF. Of the remaining 12 MSs, 9 had bTB in cattle herds, with a total prevalence of 1.12 % in 2011 (17,102 farms from a total of 1,524,638 existing bovine herds). This prevalence has increased steadily since 2007, when it was of 0.46 %. The proportion of positive herds in 2011 was the highest in the United Kingdom (9.90 % in Great Britain, 6.45 % in Northern Ireland), followed by Ireland (4.31 %) and Spain (1.17 %).

During 2011, a total of 194 cattle herds were infected by *M. bovis* in 5 of the 15 OTF MSs (one herd in Belgium, 173 in France, 3 in Germany, 13 in Poland and 4 in the Netherlands), but the threshold level of 0.1 % of positive cattle herds was not exceeded, and the MSs remained OTF according to Directive 98/46/EC.[51]

2.3.1.2. Surveillance system currently in place

Slaughterhouse surveillance with lesion detection during commercial slaughter is used as a cost-efficient method for passive surveillance of bTB in both OTF and non-OTF countries, in the latter to supplement live cattle farm testing. The finding of a tuberculous animal at slaughter initiates an investigation through skin testing of the herd of origin and any other potentially exposed animals (Schiller et al., 2010).

The detection and investigation of suspected bTB cases at meat inspection are generally important for the control of the infection anywhere within the EU:

- in non-OTF countries and regions as a supplement to regular and *ad hoc* bTB testing of animals and herds to control or eradicate the disease;
- in OTF countries and regions as a means for continuous monitoring, as required by international rules and regulations, to substantiate claims that bTB prevalence is below the required design prevalence. In these countries, MI may be the only surveillance component in

[50] Both *M. bovis* and *M. caprae* cause tuberculosis in bovines and other species, including humans. Further in the text, only *M. bovis* is mentioned, but any reference to *M. bovis*, unless the contrary is specified, also includes *M. caprae*.

[51] Council Directive 98/46/EC of 24 June 1998 amending Annexes A, D (Chapter I) and F to Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine OJ L 198, 15.7.1998, pp. 22–39

place, or it may coexist with skin testing of herds spaced at longer intervals of time (e.g. four years).

A. Surveillance of bTB in non-OTF MSs or zones thereof

Surveillance for bTB is one of the most comprehensive among all animal diseases regulated by EU legislation. MSs are required by EU law (Council Directive 77/391/EEC[52]) to have an accelerated bTB Eradication Plan fulfilling specified criteria (Council Directive 78/52/EEC[53]). Annual and multiannual programmes, including the financial contribution from the European Union, for the eradication, control and monitoring of certain animal diseases and zoonoses are presented by the MSs and approved by the EC (Commission Implementing Decision 2011/807/EU[54]).

At farm level, the surveillance system for bTB in non-OTF countries and regions includes mandatory periodic testing of herds using the tuberculin skin test, and removal and slaughter of reactors. To increase the sensitivity of detection of infected animals in zones of high prevalence, the gamma-interferon test may be used as an ancillary test in parallel with the skin test.

In MSs where infection is still prevalent, the slaughterhouse plays a substantial role in confirmation of *M. bovis* infection through detection of characteristic lesions and collection of samples for mycobacterial isolation, and efficient *post-mortem* examination of specified lymph nodes and of the lungs represents an important element of national bTB eradication programmes within the EU (EFSA, 2003). Furthermore, routine MI at the slaughterhouse of bovines from bTB-free herds contributes by detecting significant fraction of the total new bTB breakdowns in non-OTF zones, as shown by data from Ireland, the United Kingdom and Catalonia.

Data from the Irish Tuberculosis Programme for the period 1993–2001 (Good and More, 2006; Frankena et al., 2007;) show that between 27 % and 46 % of all new herd breakdowns every year were detected by slaughterhouse surveillance (in cattle from herds considered disease free on the basis of annual skin testing). In the period 2002–2003, this proportion was approximately of 30 % (Olea-Popelka et al., 2012). From 2003 to 2010, the percentage of new breakdowns detected by slaughterhouse MI remained stable between 30–36 % (Abernethy et al., 2013). Similarly, by 2010, 15.2 % (England) and 6.6 % (Wales) of all new herd breakdowns were identified as a result of current PMI techniques (Abernethy et al., 2013). In Catalonia, 5 out of 12 (42 %) and 5 out of 19 (26 %) of the new breakdowns in 2010 and 2011, respectively, were detected by slaughterhouse meat inspection of animals from farms not previously identified as infected (I. Selga, Director of Animal Health Service, Catalonian Government, personal communication 2012).

Therefore, in non-OTF zones, it can be expected that a reduction in the sensitivity of MI procedures will reduce the number of infected herds identified through PMI, with a negative effect on overall surveillance and control of bTB. Although these infected herds would potentially be detected later during field herd surveillance, faster detection may allow early controls, thereby preventing ongoing spread to other farms. Recent data also highlight the imperfect capability of field surveillance for disclosure of hidden infection in some farms (Olea-Popelka et al., 2008; Conlan et al., 2012).

[52] Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle. OJ L 145, 13.6.1977, p. 44–47.

[53] Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle Official Journal L 0, 19/01/1978, P. 0034-0041.

[54] 2011/807/EU: Commission Implementing Decision of 30 November 2011 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2012 and following years (notified under document C(2011) 8719). OJ L 322, 6.12.2011, p. 11–22.

B. Surveillance of bTB in OTF MSs or zones thereof

According to EU legislation (Council Directive 98/46/EC), when bTB prevalence falls to a certain threshold, a MS or part thereof may be declared OTF if the following conditions are met:

- The percentage of bovine herds confirmed as infected with tuberculosis has not exceeded 0.1 % per year of all herds for six consecutive years and at least 99.9 % of herds have achieved officially tuberculosis-free status each year for six consecutive years, the calculation of this latter percentage to take place on 31 December each calendar year.

- An identification system is in place making it possible to identify the herds of origin and transit for each bovine animal in accordance with Regulation (EC) No 820/97.[55]

- All bovine animals slaughtered are subjected to an official PMI.

- The procedures for suspension and withdrawal of officially tuberculosis-free status are complied with, including suspension when classical lesions of tuberculosis are seen at PMI.

With a reduction in the prevalence of bTB, there is a gradual transition from field-based surveillance on farms to surveillance by MI at the slaughterhouse, and in OTF countries/regions the detection of bTB by MI at the slaughterhouse becomes the essential element of the bTB surveillance and substantiates the official bTB freedom status. Examples of this policy may be found in OTF countries such as Australia, the USA, Canada or Germany (Corner et al., 1990; Kaneene et al., 2006; Schiller et al., 2010; Probst et al., 2011).

In Australia, surveillance at the slaughterhouse became the primary method for the detection of tuberculosis since 1975, being the most effective way of detecting residual infection in herds, and was central to success of the Australian national bTB campaign (Radunz, 2005, 2006). Tuberculin skin testing of herds with no evidence of bTB was discontinued, except on properties without adequate slaughterhouse surveillance. When infection was detected in a herd, the affected herd and trace-forward and trace-back herds were tuberculin skin tested.

Slaughterhouse surveillance has been also an important component of bTB control in the USA since the 1950s, when the prevalence was so low that skin testing became an inefficient method of detecting bTB, and the focus of the control moved to MI at meat plants (Kaneene et al., 2006). Germany attained OTF status in 1997, according to Directive 64/432/EEC.[56] According to this status, regular tuberculin testing was interrupted, and bTB surveillance is instead maintained by official veterinary meat inspection (Decision 97/76/EC[57]). Since then, a total of 118 bTB outbreaks in cattle were reported between 1997 and November 2009, of which 23 occurred in 2008. An essential part of the OTF status is maintaining surveillance at MI and reacting to suspected tuberculosis lesions. An example of this chain of events is described by Probst et al. (2011), after finding bTB lesions in one animal and confirming *M. bovis* infection in the 2008. Epidemiological investigations were initiated to detect in-contact-farms, and the data on meat inspection and possible condemnations from animals from this herd were retrospectively analysed. Comparative tuberculin skin testing of the index herd (173 animals) revealed 101 (58 %) reactors, and the herd was culled. Farms identified as contacts were subjected to skin testing. Farms neighbouring the index case were also included in the investigations. The epidemiological investigation starting from a single bTB-infected farm identified a further 11

[55] Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products. OJ L 117, 7.5.1997, p. 1–8.
[56] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine. OJ 121, 29.7.1964, p. 1977–2012.
[57] Council Directive 97/76/EC of 16 December 1997 amending Directive 77/99/EEC and Directive 72/462/EEC with regard to the rules applicable to minced meat, meat preparations and certain other products of animal origin. OJ L 10, 16.1.1998, p. 25–27.

bTB-positive herds. The authors concluded that, although bTB lesions were detected by MIs, it may not be effective enough for bTB surveillance (Probst et al., 2011).

Efficacy of detection of bTB at the slaughterhouse depends largely on the sensitivity of the MI procedures, and the subsequent efforts to submit suspected lesions to the laboratory for histopathology and/or mycobacterial culture. To increase the sensitivity of slaughterhouse monitoring, a national granuloma submission programme (NGSP) was established in Australia in 1992. This programme set a submission target of 1 granuloma for every 2000 animals slaughtered and, during the period 1992–1999, 75 % of all new cases of bTB were identified through this programme. In this period, almost 70 million cattle were slaughtered and subject to slaughterhouse inspection and only 72 (0.36 %) of the 22,022 granulomas submitted through the NGSP were caused by *M. bovis* (Cousins and Roberts, 2001). Australia achieved TB Free Area Status in 1997. This target was later revised to 1 per 1000 animals slaughtered, and sampling strategy changed to risk-based sampling, and in 2003–2004 the result was 1 submitted granuloma per 728 animals, with no bTB cases detected in the period.

Similarly to Australia, a granuloma submission programme was established in USA in 2000. The target submission rate was set at 1 per 2000 animals slaughtered. An award programme has been established, which gives financial incentives to inspectors and slaughterhouses submitting positive samples, and this is likely to have contributed to achievement of the target. This policy is considered the primary case-finding tool for bTB in the USA (USDA-APHIS-VS, 2011). The target submission rates and financial incentives are still in effect. Slaughter surveillance should be sufficient to detect a 0.05 % or lower prevalence with 95 % confidence (USDA-APHIS-VS, 2009).

2.3.1.3. Impact of proposed changes on surveillance and control

The efficacy of MI procedures for detecting *M. bovis* infection may be influenced by many factors, related to the pathobiology of the infection, the intensity of inspection, the skills and dedication of the inspector and other variables such as the speed of the chain, etc. (Corner, 1994). In current MI procedures applied in the EU, key tasks for the detection of suspected tuberculous lesions include visual inspection and palpation of the lungs, and palpation and incision of relevant lymph nodes (e.g. mediastinal, tracheobronchial, and medial retropharyngeal lymph nodes). Detailed examination (including palpation and incision) of these sites may detect as many as 85.4 % of animals with a single tuberculous lesion (primary sites of infection) (Corner, 1994). If palpation of lungs and lymph nodes and incision of lymph nodes are omitted, small suspect lesions in these organs may go undetected.

It is generally accepted that the sensitivity of the current MI system for detection of bTB is low. If a change of the current MI to a visual only system were to be introduced, it could further reduce the sensitivity of detection, making the system inefficient and unreliable for surveillance, especially in the case of OTF MSs or zones, where MI is the main or only surveillance system in place. To assess the impact of changes on the overall MI sensitivity, the following approach was followed:

- Recent scientific information was reviewed to obtain estimates of sensitivity of detection of bTB by MI, and factors affecting it.
- The information and conclusions contained in two recent reports (FSA, 2013a; COMISURV report comparing the current MI procedures with a visual only system) were reviewed.
- Finally, the effect of a reduction in the sensitivity of detection of individual animals by MI on global herd surveillance in OTF zones was modelled (see Section 2.5) to assess suitability of MI surveillance under the criteria of EU legislation (Council Directive 98/46/EC).

A. Sensitivity of the current meat inspection system for bTB surveillance

Estimates of the sensitivity of detection of bTB through MI have been published in several reports (Corner et al., 1990; Corner, 1994; Asseged et al., 2004). Comparisons between the results, however,

are difficult, partly because a common gold standard is not available and partly because inspection procedures may vary in efficiency between slaughterhouses and inspectors (Martin et al., 2003; Frankena et al., 2007; Biffa et al., 2010; Olea-Popelka et al., 2012).

A detailed necropsy procedure, which includes careful palpation and slicing of target organs, would be the most efficient *post-mortem* procedure for the detection of suspected tuberculous lesions (Corner et al., 1990). When detailed necropsy was applied to 494 cattle from 7 depopulated herds, a sensitivity of 86.05 % was obtained, using bacteriological culture or Polymerase chain reaction (PCR) (or both) as the reference test to detect animals truly infected with bTb (Norby et al., 2004). According to Norby et al. (2004), this sensitivity of necropsy as a diagnostic assay (86.05 %) can perhaps be viewed as the 'upper detection limit' of any practical slaughterhouse surveillance system for bTB. A slightly lower proportion of animals with visible lesions were found by Liebana et al. (2008), with 111 out of 200 (55.5 %) skin test reactors showing suspected tuberculous lesions after a detailed necropsy procedure.

As expected, several studies have shown that current MI procedures have lower sensitivity than detailed necropsy procedures for detection of bTB lesions (Corner et al., 1990). In an Australian study, the sensitivity of routine MI procedures was compared with the sensitivity of detailed necropsy (including dissection and slicing of lymph nodes, lungs, liver and spleen) in cattle in which intradermal or serological testing was positive, showing a sensitivity of 0.47 (Corner et al., 1990). In addition, two studies from Ethiopia compared the sensitivity of routine meat inspection with that of detailed necropsy and laboratory examination of lymph nodes, lungs, liver, mammary glands and kidneys in combination with *M. bovis* isolation as gold standard. In the first study, 1350 cattle were examined and 1.5 % showed tuberculous lesions in a detailed necropsy, but routine slaughterhouse inspection was able to detect only 55 % of cattle with confirmed lesions (Asseged et al., 2004). In the second study, 751 carcasses were examined, and 34 (4.5 %) had tuberculous lesions by detailed necropsy, but routine slaughterhouse inspection detected only 29.4 % of the carcasses with lesions (Biffa et al., 2010). In a similar study in a high-prevalence zone, detailed slaughterhouse inspection protocols improved the detection level approximately fourfold (Aylate et al., 2013).

In another study (de Kantor et al., 1987), 719 cattle from 17 farms from an endemic bTB zone were slaughtered and routinely inspected. Suspected tuberculous lesions were found in ten animals. Pools of respiratory and mesenteric lymph nodes from 178 randomly selected animals that did not show lesions by routine MI were submitted for detailed macroscopic examination and mycobacterial isolation. *M. bovis* was isolated in five of these animals, four of which had no visible lesions, and one of which showed a small granulomatous lesion in one lymph node. The sensitivity of MI was 0.67 (10 detected cases out of 15).

These studies show that the relative sensitivity of current MI procedures for detecting bTB lesions are around two- and threefold lower than the relative sensitivity of detailed necropsy.

A systematic review of relevant literature and meta-analysis was recently performed (VLA, 2011) to assess the sensitivity and specificity of different bTB diagnostic methods, among them *post-mortem* investigation. The detailed analysis of this information is also available in a recent EFSA opinion (EFSA AHAW Panel, 2012b). The results of this meta-analysis, expressed as median values (with 2.5th and 97.5th percentiles), gave a value for the sensitivity of routine MI of 0.71 (0.38–0.92). These sensitivity values were employed in the modelling of the herd-level and area sensitivity (see Section 2.5). As expected, the sensitivity of detailed *post-mortem* investigation was slightly higher, at 0.96 (0.82–1.00). Recently, Wahlström et al. (2010), based on the review of available literature of bTB, constructed models for herd-based monitoring of TB in deer using 0.29, 0.6 and 0.86 as minimum, most likely and maximum sensitivity values, respectively.

The proportion of cattle showing lesions and the proportion of suspected lesions which are in fact due to *M. bovis* (confirmation rate) are affected by the prevalence on infection in an area, and by factors related to the slaughterhouse and laboratory (Corner et al., 1990; Frankena et al., 2007; Olea-Popelka

et al., 2012). The proportion of skin test reactors not showing lesions may be as high as 10 % after a detailed necropsy (Corner, 1994), and as high as 60 % applying current MI procedures (Costello et al., 1997; Karolemeas et al., 2012). The confirmation rate of suspected lesions is different for skin test reactors than for routine slaughtered cattle. In Ireland, bTB was confirmed by laboratory tests (histopathology and/or culture) in 64.4 % of animals with suspected lesions for the period 1993–2001 (Frankena et al., 2007). The confirmation rate did not change from 2005–2007 (66.7 %, data analysed with the same methodology) (Olea-Popelka et al., 2012). A slightly higher confirmation rate of suspected lesions has been reported in the United Kingdom. Recent data from 2011 show that *M. bovis* was cultured from around 75 % of suspect granulomas detected during routine slaughterhouse surveillance (i.e. not in reactor animals identified during a breakdown) (unpublished data of DEFRA 2012, cited by Karolemeas et al., 2012), and from an estimate of 95 % of skin test reactors with visible lesions (AHVLA, 2011).

The importance of this process of confirmation of infection is higher when the prevalence of bTB is further reduced. This is because the positive predictive value of classifying a granuloma as tuberculous at MI decreases as the prevalence of bTB decreases (Corner, 1994).

B. Impact of changes in meat inspection system: the COMISURV report and the UK Food Standards Agency report

Two recent reports have dealt with the impact of changes on MI on surveillance and control of animal diseases.

The impact of the proposed changes to the current MI on the overall sensitivity of surveillance and control of animal health and welfare conditions was recently assessed by expert opinion and modelling through an EFSA procurement (the COMISURV report) (see Section 2.2) because of the lack of empirical data on the sensitivity of a visual only MI system. This quantitative assessment determined for bTB a significant decrease in the capability of detection of MI when moving from the current to a visual only system, with a fivefold reduction in the detection fraction (Table 3). This effect is more prominent for milder cases of bTB. Scores given by experts to the detection fraction with 90 % probability intervals were 0.052 (0.032–0.083) for the current system, with a fivefold reduction to 0.010 (0.005–0.017) when moving to a visual only MI. This reduction would have an impact on the effectiveness of surveillance. The magnitude of this effect on the overall surveillance of bTB may be different for OTF than for non-OTF MSs and zones thereof.

A qualitative risk assessment was commissioned by the UK Food Standards Agency (FSA) to determine the implications of a change to a visual only inspection system on the surveillance of animal diseases (FSA, 2013a). The experts considered that there was a potential increase of the risk to animal health/welfare in the case of bTB, ranked from very low to low, but with considerable uncertainty. A move to visual only inspection would reduce the number of bTB cases found at the slaughterhouse using sensorial PMI. However, the overall impact that this reduction will have on the surveillance and control system of bTB is difficult to ascertain.

The magnitude of the negative effect could be different depending of the origin of the animals, i.e. whether they come from non-OTF or from OTF areas. In the United Kingdom, for example, animals from non-OTF farms in high-risk areas will be subjected to a skin test every year, whereas animals in low-risk OTF areas will be tested once every four years. As a result, it is expected that in non-OTF areas infected herds will be detected relatively quickly through the mandatory skin test, limiting spread of the infection within the herd and to other herds. However, in OTF areas, there is a higher probability of infection becoming relatively widespread in the period between skin tests, and a higher infection risk to other herds through animal movements. This is confirmed by data showing that the number of herds that lost their OTF status is higher (45.4 %) for herds from low-risk areas where a tuberculin skin test is carried out every four years than for herds from areas tested annually (21.3 %) (AHVLA, 2011; FSA, 2013a).

Similar conclusions were drawn in previous assessments of EFSA, in which it was concluded that omission of palpation or incisions as performed under current MI legislation would reduce the detection rate of tuberculosis in bovines, and therefore would negatively affect animal disease control.

2.3.2. Cysticercosis

2.3.2.1. Description of the condition and prevalence and relevance in EU

Bovine cysticercosis is caused by the larval stage of *Taenia saginata*, a tapeworm inhabiting the small intestine of humans, who act as the final host for the parasite. After oral infection, bovines develop cysticerci in striated muscle and to a lesser extent in other organs, including liver and lungs (Scandrett et al., 2009). Humans become infected by eating raw or undercooked bovine meat or offal containing viable cysticerci (Cabaret et al., 2002). The intestinal infection in humans is subclinical or causes very mild clinical signs. Transmission to cattle occurs through contamination of feed, water or the farm environment with eggs of the parasite. Although direct transmission from the faeces of infected humans may occur (Slonka et al., 1975, 1978), faecal samples from farm staff have not shown infection by *T. saginata* in most of the outbreaks investigated (Lees et al., 2002; McFadden et al., 2011). It is likely that indirect contamination by infective eggs in sludge from treatment plants and sewage is a more relevant way of contamination of pastures and farm environment (Cabaret et al., 2002). Sewage sludge contains viable eggs of *T. saginata*, and calves can be infected orally with contaminated sludge given *per os* (Moussavou-Boussougou et al., 2005). Therefore, control of exposure of cattle requires strict measures of treatment and full inactivation of eggs in sewage treatment plants (Cabaret et al., 2002).

Bovine cysticercosis prevalence in the EU, based on slaughterhouse data, ranges from 0.01 to 6.8 % (SCVMPH, 2000), with a great variation between countries and regions. In a survey conducted in northern Spain during 1992 and 1998, a prevalence of 0.54 % was observed, with fairly low variation between years (range 0.41–0.75) (Moreno-Garcia, 2003). A lower prevalence was found in Catalonia in the period 2005–2007, ranging from 0.015 to 0.022 % (Allepuz et al., 2009). Prevalence in northern Italy during 1999–2000 was 0.19 % (EFSA, 2004). Recent data from the Belgium Federal Agency of Security of the Food Chain from the period 2001–2005 showed prevalence at meat inspection ranging from 0.22 % to 0.44 % (Boone et al., 2007). In an epidemiological study carried out in the same country between 2001 and 2003 to determine risk factors for bovine cysticercosis, as many as 973 case herds (defined as a herd with at least one homebred animal infected) were found from a total of 5080 herds (19.1 % of the farms), with as many as 1252 infected animals. Infected herds were distributed through the whole study area, and their number increased from 2001 to 2003 (Boone et al., 2007).

In general, within-herd prevalence has been low in all the studies performed across the EU, although clustering of cases in a herd or a region may occur, attaining within-herd prevalences of up to 11 % (Slonka et al., 1975, 1978; Yoder et al., 1994).

It is generally accepted that data collected during routine MI procedures cannot be considered an accurate approximation to the true occurrence of bovine cysticercosis in the EU (EFSA, 2004). If the low sensitivity of MI for detecting bovine cysticercosis is taken into account (see Section 2.3.2.3 below), the true prevalence of *T. saginata* cysticercosis in the EU may be higher. Serological techniques have been developed that allow on-farm detection of *T. saginata* cysticercosis, with apparently a much higher sensitivity than routine MI. Antigen-capture-Enzyme-linked immunosorbent assays (Ag-ELISA) techniques (detecting either excretory–secretory antigens or somatic antigens) are preferred to standard antibody-detecting ELISA (Van Kerckhoven et al., 1998; Dorny et al., 2000; Ogunremi and Benjamin, 2010). The sensitivity and specificity of these tests may be around 92–93 % and 90–98 %, respectively, but the sensitivity is strongly reduced in populations with a low parasite burden. Using this test on a sample of 1164 cattle at Belgian slaughterhouses, a prevalence of 3.09 % was observed, whereas the estimated prevalence by routine MI was only 0.26 % (Dorny et al., 2000). In a Canadian survey, estimated prevalence was 4.6 % (95 % CI 0.5–10.3 %) (Ogunremi and

Benjamin, 2010). Large differences in prevalence were obtained in a sample of 2073 routinely inspected cattle in Catalonia: 1.1 % (95 % CI 0.8–1.8 %) by ELISA, and 0.02 % (95 % CI 0.01–0.03 %) by routine MI (Allepuz et al., 2012). Prevalence as measured by Ag-ELISA may be at least 10 times higher than that observed by MI.

Although human *T. saginata* infection and bovine *T. saginata* cysticercosis are interdependent, there are no estimations of the impact of control measures at any point of the biological cycle of the parasite. The low morbidity in humans, the low sensitivity of meat inspection for detecting infected cattle, and the widespread environmental contamination through sewage sludge are probably factors contributing to the persistence of *T. saginata* in humans and in bovine farms (Cabaret et al., 2002).

2.3.2.2. Surveillance system currently in place

In practice, information about prevalence of bovine cysticercosis is currently collected only at slaughterhouses. Bovine animals over six weeks of age are inspected at the slaughterhouse by visual examination, palpation and incisions (masseter muscles, tongue, diaphragm and heart) for detection of *T. saginata* larval stages, with the aim of protecting humans from ingestion of viable cysticerci and development of intestinal taeniasis. Freezing of the carcass and offal is prescribed in the case of a mild infection, but in the case of heavy infections the carcass and offal are condemned.

The sensitivity of the current MI for the detection of bovine cysticercosis is considered to be low, and is affected by the number of cysticerci harboured by infected animals (lower sensitivity for animals having lower number of cysticerci), by the skill and awareness of meat inspectors and by the quality of inspection (Allepuz et al., 2009). Routine MI and detailed dissection and slicing have been compared in several studies with both naturally and experimentally infected bovines. Routine MI was able to detect between 17 % and 71 % of the animals classified as infected using detailed dissection and slicing (Jepsen and Roth, 1950; Walther and Koske, 1980; Wanzala et al., 2003; Scandrett et al., 2009; Soares et al., 2011). This wide range of sensitivities may be due to differences in the parasite load, or to different MI procedures in different countries.

2.3.2.3. Impact of proposed changes on surveillance and control

In the current MI procedure according to EU legislation, myocardial and masseter muscle incisions are the inspection tasks where the inspector is seeking to detect bovine cysticercosis, if present. Moving to a visual only system would omit these incisions, and further reduce the sensitivity of *T. saginata* cysticercosis surveillance of the current MI system. The quantitative assessment carried out for this opinion determined a significant decrease in capability of detection of MI when moving from the current to a visual only system, with a fourfold reduction in the detection fraction (Table 3). The impact of this change will be a further decrease in sensitivity of detection, making prevalence data unreliable. Further, the expected increase in the number of carcasses with viable cysticerci declared fit for human consumption (see Annex B, Section 5.4.1, for a detailed analysis) may contribute indirectly to an increase in the prevalence of infection in bovines in the EU, with the consequent associated losses due to meat condemnation or to inactivation treatments. Alternative options to a change to a visual only system would be to cease incisions of the carcass, but increase inspection of the heart by making additional incisions. There is preliminary evidence that this practice could ameliorate the loss of sensitivity if incisions of carcass muscles were no longer done (Eichenberger et al., 2011).

A focus on food chain information through inclusion of risk categorisation of cattle regarding bovine cysticercosis would allow current (or even more stringent) procedures to be applied to animals, batches or farms of high risk, and, therefore, the omission of incisions when inspecting low-risk farms. Risk categorisation may guide future data recording to be included as FCI, enabling development of risk-based meat inspection systems. FCI could, for example, include results of serological investigation for *T. saginata* antigens, or information about other known risk factors for bovine cysticercosis. In a case–control study of risk factors for bovine cysticercosis in Danish cattle herds (Calvo-Artavia et al., 2012a), grazing outdoors, access of animals to risky water sources with sewage

treatment plant effluent in proximity and a low herd size were identified as significant risk factors. In another Danish study, factors associated with the occurrence of bovine cysticercosis were investigated in a total of 348 bovine cases detected at slaughter between 2004 and 2011. At the animal level, significant risk factors included sex and age, with female animals and older animals having a higher risk of cysticercosis (Calvo-Artavia et al., 2012b). Incorporating these results, these authors developed a stochastic scenario tree simulation model to evaluate the performance and economic benefit of a risk-based surveillance system for detection of bovine cysticercosis The surveillance sensitivity of the risk-based scenarios was only slightly lower than the sensitivity of the current system, but feasibility was highly dependent on the capability of the facility to reorganise the work at the slaughter line depending of the risk category of the slaughtered animal (Calvo-Artavia, 2013). As expected, the investigated scenarios for risk-based MI would not improve detection capability of cysticercosis cases at the actual current sensitivity of the system. Therefore, these authors highlight the need to improve the sensitivity of the methods used for inspection of high-risk cattle on a risk-based MI.

2.3.3. Fasciolosis

2.3.3.1. Description of the disease and prevalence and relevance in EU

Liver fluke disease, or fasciolosis, is one of the most important parasitic diseases of grazing animals. It is caused by a flatworm, *Fasciola hepatica*. The economic and social impact is immense, with substantial worldwide production loss and over 600 million animals infected (Borgsteede, 2011). Liver fluke infestation can assume an acute, subacute or chronic form. Animals heavily infected with *F. hepatica* may die, while very many more that are less severely affected can suffer a substantial reduction in growth rate, milk yield and fertility (Gracey and Collins, 1992; Goodall et al., 1993; López-Díaz et al, 1998). Unlike sheep, cattle rarely suffer from acute infestation and generally present with chronic subclinical infestation (Borgsteede, 2011). There has been a noticeable rise in the incidence of fasciolosis in recent years, as documented in a number of countries in Europe (Borgsteede et al., 2005; Thomas et al., 2007; Kenyon et al., 2009). Studies indicate that fasciolosis in cattle is underdiagnosed by clinical surveillance and that its prevalence, as determined by PMI can be unexpectedly high. One such study of dairy cows in Ireland found an incidence of 65 % at *post-mortem* surveillance in the slaughterhouse (Murphy et al., 2006). An earlier study by Ross (1966) found that 88 % of adult cattle had been infected by *F. hepatica* at some stage in their life, based on liver examinations at slaughter. Gracey and Collins (1992) reported that liver fluke caused the rejection of approximately 29 % of bovine livers in England and Wales. Rapsch et al. (2006) found that 18 % of cattle presented at two slaughterhouses in Switzerland had *F hepatica* and concluded that infestation was underdiagnosed. These variations in prevalence can be explained by many variable factors: climatic conditions, availability of effective fasciolicides and animal husbandry (Blamire and Goodhand, 1980). Greater awareness of the losses caused by liver fluke among farmers has a significant effect on the occurrence and control of fasciolosis in meat animals (Schweizer et al., 2005). Therefore, the provision of accurate *post-mortem* disease surveillance information has a role in animal health protection. At present there are low rates of feedback to farmers regarding *F. hepatica* (FSA, 2013a).

2.3.3.2. Surveillance system currently in place

The provision of effective monitoring systems is necessary to provide reliable information on diseases, which is vital in protecting a nation's agricultural system and its potential for production (Glosser, 1988). Information on fluke populations and risk of infestation at herd and regional levels may allow farmers to develop and implement control programmes that can attempt to reduce risk factors and recommend the use of drugs in a more strategic fashion (Fairweather, 2011). Serological techniques using indirect immunoenzymatic diagnosis have a high sensitivity and specificity and represent an important contribution to the early detection of infection with *F. hepatica* (Sanchez-Andrade et al., 2000). However the present PMI procedure is the most effective tool in routine liver fluke surveillance in cattle. This procedure, as defined by Regulation (EC) 854 of 2004, involves the visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes, and the incision of the gastric

surface of the liver to examine the bile ducts, where adult flukes reside. Rapsch (2006) determined the sensitivity of liver fluke surveillance to be 66 %. Although effective, he concluded that this method lacks the sensitivity of laboratory-based methods. However it is routinely carried out at slaughterhouses and therefore is an important monitoring point. Rapsch suggested that meat inspectors may be finding the more heavily diseased livers and other infected cattle, not being picked up by the present technique may be less affected by the parasite, thereby accounting for the lower sensitivity. It would therefore be appropriate to conclude that a less sensitive, 'visual only', inspection of the liver would result in a further reduction in the detection rate for liver fluke in bovines.

2.3.3.3. Impact of proposed changes on surveillance and control

A reduction in the sensitivity of liver fluke detection arising from the use of visual only MI, will result in a reduction in the information being made available to producers on the fluke burden in their animals. This has both an animal health and an animal welfare implication. Cattle show a higher prevalence of chronic fluke than sheep, and therefore adult flukes are commonly found in the bile ducts of infected cattle. Visual inspection may be effective in diagnosing profound bilary calcification; however, less pronounced infestations may go undetected. Schweizer et al. (2005) determined that fluke infestation is associated with a significant financial cost. Most of these losses arise from reduced milk yield and reduced fertility in affected animals, and smaller losses are due to reduced meat production and the condemnation of livers. Therefore, the reduced sensitivity of surveillance has production and resultant financial implications. However, feedback to farmers regarding *F. hepatica* infection is currently low enough that, in practice, the risk to animal health/welfare of this disease that would result from including non-conforming systems under the visual only PMI is probably negligible (FSA, 2013a).

2.3.4. Respiratory diseases

2.3.4.1. Description of the disease and prevalence and relevance in the EU

Respiratory disease is common in most livestock around the world. Respiratory disease in cattle is caused by a complex interplay of several factors including microbial agents, host factors, management factors and the environment (Carrington, 2007). Respiratory disease can present as several clinically definable syndromes; however, the complex of viral, bacterial and mycoplasmal infections has led to the development of blanket terms such as 'enzootic pneumonia' or the 'bovine respiratory complex' often being used (Barrett, 2000). The infectious agents associated with bovine respiratory disease are ubiquitous in the cattle population and the bacteria most often associated with pneumonic lesions are part of the normal resident flora of the nasopharynx of cattle (Ames et al., 2002). Respiratory disease is the single most important cause of morbidity and mortality among feedlot cattle worldwide and is reported to account for 65 % of diseases in feedlots (Gardner et al., 1999; Carrington 2007; Gay et al., 2009). In a North American study, 35 % of cattle received treatment for respiratory disease, on the basis of their clinical appearance, at some time between birth and slaughter. When they were slaughtered, 78 % of these treated animals had evidence of pulmonary lesions compared with 68 % of untreated cattle (Wittum et al., 1996). This result suggests that the performance of 'clinically healthy' cattle may also have been reduced by subclinical disease. This suggestion is supported by Griffin (1997), who reported that in one study 50 % of cattle that had never been diagnosed as having respiratory disease during life had gross lung lesions at slaughter; he also reported a significantly lower average daily weight gain in the animals with lung lesions. It would appear from these reports that cattle with lung pathology sufficient to reduce their performance may often go undiagnosed and untreated (Barrett, 2000). In a similar French study (Gay et al., 2009), 10 % of herds in a representative sample of herds were found to show evidence of respiratory disease.

2.3.4.2. Surveillance system currently in place

A very effective method of detecting chronic pneumonia and pleurisy in cattle is to carefully examine the lungs at slaughter. It is now recognised that such inspections also play an integral role in

assessment of animal health and zoosanitary status, as well as detection of certain welfare conditions (Alban et al, 2011). The current routine meat inspection procedure for cattle involves a visual inspection and palpation of the lungs with incision and examination of the bronchial and mediastinal lymph nodes. When the lungs are processed for human consumption, the trachea and the main branches of the bronchi must be opened lengthways and the lungs must be incised in their posterior third, perpendicular to their main axes (Regulation (EC) No 854/2004). The palpation and incision of the lungs and related tissues improves the possibility of detecting discrete lesions (Corner, 1994).

2.3.4.3. Impact of proposed changes on surveillance and control

Validation studies on visual only meat inspection diagnosis of respiratory conditions in sheep showed it to be of relatively low sensitivity, but of high specificity, and therefore the true pneumonia prevalence of the population was underestimated (Goodwin-Ray, 2008). In the case of cattle, where palpation and incision plays a greater part in traditional meat inspection than in sheep, one would expect a more profound underestimation. Using visual only meat inspection, the detection of moderate to severe pneumonia is more reliable than that of minor pneumonia. This suggests that the visual only assessment of pneumonic lesions by meat inspectors at slaughter has limitations as a diagnostic tool (Goodwin-Ray, 2006).

MI data play an important role in informing herd health programmes, thereby reducing the risk of injury and disease and improving production efficiency. Such data could contribute to reduced losses to producers and processors through lower rates of carcass condemnations, trimming and downgrading in conjunction with higher welfare standards on-farm. Currently meat inspection data are underutilised in the EU, even as a means of informing herd health programmes (Harley et al., 2012). The removal of palpation and incision of the lung tissue and lymph nodes would further erode the sensitivity of the present meat inspection system (as documented in Regulation (EC) No 854/2004). This would reduce the validity of the feedback of disease information, which is of primary economic interest to producers (Mousing et al., 1997).

2.3.5. Welfare conditions

Detection of welfare conditions included in the quantitative analyses was not found to be affected by the proposed changes to PMI. This is because seven out of eight welfare conditions (i.e. bruises and injury, cleanliness score, foot and leg disorders, fractured limb, integument alterations and low body condition) can be detected during AMI inspection and detection of DFD is not part of the routine PMI in EU slaughterhouses. Nevertheless, it is thought that a qualitative assessment of welfare conditions would be beneficial.

AMI of animals slaughtered for human food is covered by the EU Regulation (EC) 853/2004[58] and should be carried out within 24 hours of arrival of the animals at the slaughterhouse and less than 24 hours before slaughter. If AMI or PMI reveals the presence of any disease or condition that might affect public or animal health or indicate compromised animal welfare, the Official Veterinarian (OV) should inform the slaughterhouse, referred to as the food business operator (FBO). The FCI and collection and communication of inspection results (CCIR) together constitute the information cycle and is required by Regulations (EC) 852/2004,[59] 853/2004 and 854/2004. The EC Implementing Measures Regulation (EC) 2074/2005 requires the competent authority to inform the dispatching FBO of the minimum elements of FCI to be supplied to the slaughterhouse.

The objectives of the AMI in the current hygiene legislation, Regulation (EC) 854/2004, are to determine "*conditions that might adversely affect human or animal health, paying particular attention*

[58] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30.4.2004, p. 55–205

[59] Regulation (EC) No 852/2004 of the European Parliament and of th.e Council of 29 April 2004 on the hygiene of foodstuffs. OJ L 139, 30.4.2004, p. 1–54.

to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Union legislation, and whether there is any sign that welfare has been compromised".

However, at the moment, a list of animal based indicators (ABIs) of welfare, or guidance to their detection are not available for scientific validation/review. From 1 January 2013, the welfare of animals in slaughterhouses is governed by the new EU Slaughter Regulation (EC) 1099/2009.[60] This regulation places the onus on the FBO and designated animal welfare officers to ensure that the animal welfare is not compromised from the time of arrival to slaughter; the OV will be responsible for risk-based assessment of compliance with the regulation. The regulation also requires that the MSs prepare and implement a guide to good practice, and standard operating procedures should also be prepared by the FBO. Therefore, the existing situation may change and monitoring of animal welfare using ABIs could be implemented during AMI in slaughterhouses.

In recent years, there has been a steady decline in the number of cattle slaughterhouses in the EU and, as a consequence, cattle transport distance and duration have been increasing (see also BIOHAZ Panel appendix). Marketing of cattle through auction markets leads to extended transport duration and increases the number of occasions the animals are loaded, unloaded, driven and mixed with unfamiliar animals in unfamiliar environments. All these factors adversely affect animal welfare and can cause physical injury. Young calves are particularly vulnerable, and losses due to mortality can be high due to transport (Knowles, 1995). Nevertheless, the welfare of animals during transport and related operations is controlled in the EU by Regulation (EC) 1/2005.[61]

Animals showing signs of fatigue or stress must be rested for not less than 24 hours unless the OV has determined otherwise. It is well established that agonistic and antagonistic interactions occurring between mixed groups of unfamiliar cattle, especially bulls, lead to fatigue and produce carcasses with DFD meat (Kenny and Tarrant, 1987a, b). Under this situation, slaughter of animals immediately after unloading in slaughterhouses or keeping the duration of lairage to a minimum would be beneficial to animal welfare and meat quality. Familiar group of cattle subjected to extreme distress due to rough handling and transport also produce carcasses with DFD meat (Tarrant et al., 1992; Warriss et al., 1995). It should be possible for the OV to detect these animals during routine examination of FCI, and they should be rested and given adequate food and water to recover from the fatigue prior to slaughter.

Bruises can occur in cattle due to poor handling on the farm or at the auction market, during loading , poor transport conditions (e.g. poor road condition, sudden changes in acceleration, braking and cornering), unloading at the slaughterhouse, lairage and even during restraining for the purpose of application of stunning procedures (Jarvis et al., 1995, 1996; Strappini et al., 1999). Cattle prefer to stand during transport but they do lie down during long journeys. Overcrowding and slippery floors in transport vehicles can cause cattle to fall and, if they do not have room or the opportunity to stand up again, this increases the chance of other animals trampling on them. Fractious animals and those that are not used to being in close proximity with humans and/or handled by them are more prone to bruising. The use of sticks, rod or electrical prodding devices increases the chances of bruising (Knowles, 1999). The depth and severity of bruising may vary depending on several factors, including the presence of horns, and several bovine carcass bruise-scoring systems have been developed and used worldwide to suit commercial purposes. However, none of them would appear to be designed to address the welfare consequences.

Lameness and mobility problems in dairy cows are prevalent and the problem could be due to sole bruising, sole ulcer, white line, fissures, digital dermatitis, inter-digital growth, slurry heel or foul. In general, the causes of lameness are multifactorial, but are generally recognised as poor quality floors

[60] Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (Text with EEA relevance). OJ L 303, 18.11.2009, p. 1–30.

[61] Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97. OJ L 3, 5.1.2005, p. 1–44.

in cattle housing, poor cow tracks, cows being forced to stand for too long on hard surfaces, poorly-designed cubicles, ineffective foot trimming, infectious diseases and poor nutrition (EFSA, 2009a, b, c, d, e, f). It is worth noting that ABIs have been proposed (EFSA 2012c; EFSA AHAW Panel 2012d) for the assessment of dairy cow welfare, especially lameness, and these could be applied in slaughterhouses also.

Measurements of physiological stress indicators have suggested that transport of cattle by road for 31 hours is not excessively demanding and that a 24-hours rest period in lairage, with hay and water freely available, allows the animals to recover, although not completely (Knowles et al., 1999). Since recovery from the stress of long-distance transport is a slow and incomplete process, the recommendation for shortened transport time and, as a consequence shortened lairage time, would be beneficial to animal welfare.

2.4. Food chain information

The EU Regulation (EC) No 852/2004 on the hygiene of foodstuffs requires slaughterhouse operators to request FCI declarations to ensure animals entering the food chain are safe for human consumption. FCI is also a good source of information to facilitate the detection in the slaughterhouse of abnormalities indicative of animal health and welfare conditions. FCI is recorded at the herd level, and its minimum content is described in Regulation (EC) No 853/2004. FCI related to primary production of cattle is based on a farmer's declaration. Most MSs have made available to farmers a standardised FCI declaration form. A whole-chain approach to food safety, animal health and animal welfare requires FBOs to be provided by livestock producers with information about their animals consigned to slaughter. Based on the FCI provided, slaughterhouse operators can assess potential hazards presented by the animals and are required to act upon any information recorded on the FCI declaration as part of their Hazard Analysis and Critical Control Point (HACCP) plan. This helps the slaughterhouse operator to organise slaughter operations and to ensure that no animals affected by disease or certain veterinary medicines enter the food chain. Quality assurance schemes at primary producer level are voluntary tools operated by independent agencies or bodies to ensure compliance with given standards and regulations. These schemes increase farmers' responsibilities with regard to animal health and welfare and have potential for integration within the FCI provided (OIE, 2006).

The FCI also assists risk management to determine the required inspection procedures and should be analysed by risk management and used as an integral part of the inspection procedures.

The value of the FCI in guiding risk management to discriminate between animals subsequently going through different types of inspection procedures should be evaluated. As for any evaluation of (pre-) screening procedures, the sensitivity and specificity of the classification should be estimated. Priority should be given to improving test sensitivity, noting that (pre-) screening tests should preferably produce few false negative classifications for the sake of animal disease detection and surveillance. Testspecificity will largely be an economical parameter, since the subsequent inspection of all 'FCI-positive' animals or groups should detect any false positives not correctly identified during the FCI pre-screening.

Regulation (EC) No 853/2004 requires that data from the AMI and PMI at the slaughterhouse is delivered back to the farmer/producer when the inspections reveal the presence of any disease or condition that might affect public or animal health, or compromise animal welfare. Currently, this feedback of information to primary producers is not fully implemented in all MSs (EFSA BIOHAZ, CONTAM and AHAW Panels, 2011). The UK FSA has carried out a study on the implementation of FCI since 2006 to explore ways of improving it (FSA, 2013b). This study concludes that the effective and efficient flow of information provides valuable information to both the farmer and the FBO and allows more targeted and effective inspection procedures in the slaughterhouse and effective interventions on the farm that should contribute to a cycle of continuous improvement with positive implications for animal health and welfare. The effectiveness of this information cycle depends on a

reliable animal identification and recording system at the slaughterhouse and an information transfer system to the primary producer. The collection and communication of slaughterhouse inspection results is an opportunity to collect and use data and knowledge applicable to disease control and the effectiveness of interventions, animal production systems, food safety and animal health/welfare (Garcia, 2012). At national and EU level, such data can contribute to disease surveillance (for the detection of exotic diseases, monitoring of endemic diseases and identification of emerging diseases) and targeted animal health and welfare interventions. Therefore, FCI, if consistently and effectively implemented as enshrined within the hygiene package, will form an integral part of a risk-based MI system.

Extended use of FCI has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only PMI is applied. For the FCI to be effective it should include species-specific indicators for the occurrence of disease and welfare conditions. FCI for public health purposes may not have an optimal design for the surveillance and monitoring of disease and welfare conditions; therefore, an integrated system should be developed whereby FCI for public health and for animal health and welfare can be used in parallel, more effectively.

2.5. Modelling the impact of a change in MI sensitivity on the surveillance of bTB at the country level

All assessments performed up to now conclude that the change to a visual only MI system will reduce the detection capability of bTB at the slaughterhouse. In some reports (as in the COMISURV report), it has been estimated by stochastic models that the change would cause a fivefold reduction in the sensitivity of MI (test sensitivity) at the animal level. However, the overall impact of this test sensitivity reduction on the MI-based surveillance of bTB is uncertain (FSA, 2013a), and has not been previously quantitatively assessed.

As previously reviewed in this opinion, the bTB surveillance strategy in OTF countries/regions relies mainly on detection of residual *M. bovis* infection at the slaughterhouse by current MI procedures. Practical experience from several OTF countries shows that surveillance based on MI and subsequent trace-back of the infection to other farms provides sufficient data for sustaining the OTF status. In some non-EU countries, however, the detection of suspected lesions and submission of samples to the laboratory is actively encouraged by providing incentives (see Section 2.3.1.2).

The suitability of slaughterhouse surveillance for bTB has recently been compared with other surveillance components in Belgium, which is an OTF country (Welby et al., 2012). The authors analysed four different active surveillance components for bTB in a stochastic scenario tree simulation model. The four scenarios were (i) farm testing only during the winter screening, (ii) testing only imported cattle, (iii) testing only purchased cattle, and (iv) screening only of all slaughtered cattle by MI. From the simulations and the results of the external validation model, it was concluded that surveillance by MI provides the best sensitivity for Belgium. The large sampling coverage was considered an important factor in explaining the high sensitivity of this component (Welby et al., 2012).

In collaboration with the Scientific Assessment Support (SAS) Unit of EFSA, a model was implemented with the aim of assessing the impact of different meat inspection options on the overall sensitivity of a bTB surveillance system in OTF countries (EFSA, 2013). The conditions that MSs or zones thereof must meet if OTF status is to be granted and sustained are specified in EU legislation. Council Directive 98/46/EC, in Annex I, lists the conditions for a MS or region of a MS to be OTF. Point (a) states "*the percentage of bovine herds confirmed as infected with tuberculosis has not exceeded 0.1 % per year of all herds for six consecutive years […], the calculation of this latter percentage to take place on 31 December each calendar year*". In addition, in point 5 it is stated "*The MS or part of a MS will retain officially tuberculosis-free status if the conditions […] continue to be met*".

In other words, each country, or part thereof, has to implement a surveillance system in order to demonstrate on a yearly basis that the prevalence of positive herds in the area does not exceed the threshold set by legislation (i.e. 0.001). Many studies have provided the principles and methods for the SAS model to assess the impact of the two meat inspection options under investigation (i.e. current and visual only) on the surveillance system sensitivity[62] at country level (or part of it) (Cameron et al., 1998; Cannon, 2001, 2002; Martin et al., 2007; Cameron, 2012).

Basically, the assessment was done by estimating the overall system sensitivity under the two different MI options (as if they were two different tests with different test sensitivity values) using all the relevant parameters:

- the design herd prevalence, i.e. the threshold for infected herds (as included in current EU legislation to define the surveillance goal, i.e. for a country to be recognised as OTF);
- the number of herds in the country;
- the size of the herds;
- the within-herd prevalence and
- the proportion of bovines sent to the slaughterhouse.

The surveillance system sensitivity values that were obtained could then be compared and evaluated in terms of the overall ability of the system to detect an actual prevalence of positive herds greater than the one requested by the legislation or, from a more appropriate perspective, the confidence that the actual prevalence is below the threshold, given that no animal tested positive at the slaughterhouse. For a detailed explanation of the model, see EFSA (2013).

It must be clear that this evaluation does not deal with the interpretation of the outcomes of the MI procedures. In particular, the aim of this assessment is not to suggest decisions to be taken in the event that an animal is found to be positive at slaughterhouse. The consequences of the adoption of the visual only (VO) system will be evaluated in terms of confidence, i.e. the probability that the actual prevalence is below the threshold set by the relevant regulation, given that all animals tested negative.

[62] Surveillance system sensitivity: the ability of the surveillance system of detecting at least one positive unit (herd) when the actual prevalence is greater than the design prevalence.

2.5.1 Methodology and theory

The first step to calculate the system sensitivity is to calculate the herd sensitivity using Formula 1:

$$HSe_i = P(T+; WHPrev) = 1 - [1 - (TestSe \cdot WHPrev)]^n$$

where HSe_i is the herd sensitivity for herd "*i*", *TestSe* is the sensitivity of the test, *WHPrev* is the prevalence of positive animals within a herd and *n* is the number of tested animals.

The herd sensitivity is the ability of a round of tests (precisely, *n* tests) to detect at least one positive animal when the actual within herd prevalence is above a given threshold (*WHPrev).*

This herd-level sensitivity value can be interpreted as the level of confidence when stating that a herd can be considered OTF after *n* negative tests. For example, if the calculated herd sensitivity is equal to 95 %, it can be assumed with a 95 % confidence level that, after a round of all negative tests, the prevalence in that herd is below the expected design prevalence (*WHPrev*). If this was not the case (i.e. the actual prevalence is above *WHPrev*), at least one animal should have tested positive (with a 95 % probability).[63]

Once the herd sensitivity is calculated for all the herds within the area of interest, these values can be combined to calculate the system sensitivity (see Formula 2):

$$SSe = 1 - \prod_{i=1}^{w} [1 - (BHPrev * HSe_i)]$$

where *SSe* is the system sensitivity, *w* is the number of herds in the area of interest, *BHPrev* is the prevalence of positive herds in the area, i.e. the prevalence of herds with an actual within prevalence above *WHPrev*, and HSe_i is the herd sensitivity for herd *i*.

The *SSe* expresses how confident one can be when stating that the herd prevalence is below the threshold, given that all herds tested negative. If this was not the case (i.e. the prevalence of positive herds is above BHPrev), at least one herd would have tested positive (i.e. one or more animals in one or more herds would have tested positive with a 95 % probability). This would be the parameter of choice when comparing the ability of different MI systems to substantiate the continued OTF status of a country/region.

The overall scenario is schematically illustrated in Figure 1. Each country (squares) has a given number of bovine herds (circles). Considering only the OTF MSs, the prevalence of positive herds against which the surveillance activity has to be designed (design prevalence) is 0.001, as specified in the EU regulation. This allows us to evaluate the ability of the meat inspection system to detect, with an acceptable level of confidence,[64] at least one positive herd when the prevalence of bTB-positive herds is greater than 0.1 %. It is chosen as our standard procedure for comparing the detection ability of different meat inspections systems at the proper level of aggregation, i.e. at the herd level, which is determined by the OTF regulation. From each herd, including the positive ones, a proportion of animals are sent to the slaughterhouse each year (slh). Using Formula 1, the *HSe* for each herd is

[63] Note: in a hypothesis testing framework such as this one, the reverse interpretation is not true, i.e. when a positive animal is found it is not possible to state that the actual prevalence is above the threshold. It is only possible to conclude that the prevalence is above 0 (zero). Further investigations are needed to estimate the actual prevalence.

[64] Note: a confidence limit of 95 % was used in the present modelling exercise although no value is indicated in the relevant EU legislation.

calculated. Combining the different herd sensitivity values (Formula 2), it is then possible to calculate the *SSe* (referred to as area sensitivity, as it is the sensitivity of a MI surveillance system implemented in an area of interest, i.e. at country level or part of it). Clearly, different values for the carcass level test sensitivity will have an impact on the *HSe* and on the *ASe*.

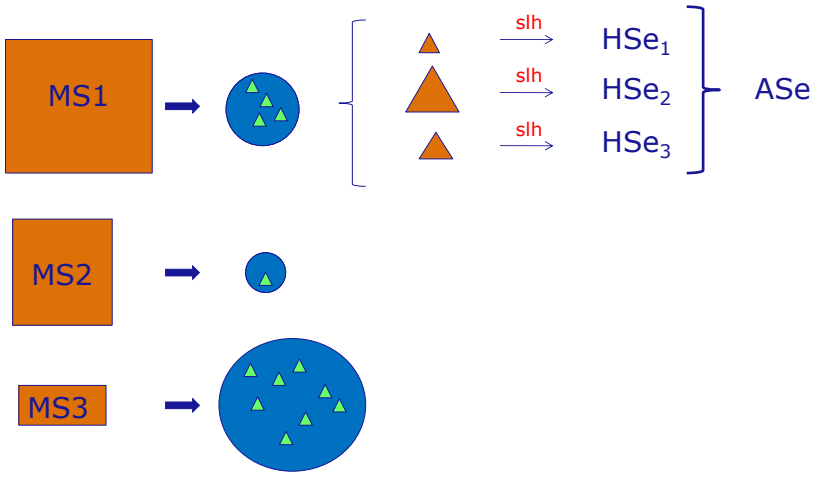


Figure 2: Overall scenario. MS = country; circles = total number of herds; triangles in the circles = negative herds; triangles = positive herds (0.001 of the total number of herds); slh = average proportion of animals sent to the slaughterhouse; *HSe* = herd sensitivity; *ASe* = area sensitivity (country, or part of it).

2.5.2 Model steps and assumptions

The simulation model is rather simple and the steps are briefly listed below:

Step	Description	Assumptions
1	Simulation of different scenarios where the area of interest (MS or part of it) is characterised by a certain number of bovine herds	The number of herds per country was obtained from Eurostat data and dated from 2007. It was assumed that the figures did not change significantly
2	Simulation and assignment of the herd size to each of the herds included in the area of interest	The probabilistic distribution of the herd size used in the simulation derives from a modelling exercise on data submitted by Belgium, Denmark and the United Kingdom. It was assumed that the fitted distribution was representative of the European scenario

Step	Description	Assumptions
3	Random selection of a proportion of positive herds within the area of interest (0.1 %). The random process ensures that the herd size distribution will be representative of the whole country	It is assumed that all herds have the same probability of being infected, regardless of their size. Although in reality the probability of infection may vary according to the herd size, many other factors may have an impact on the within-herd probability of infection (e.g. production type, age of the animals). Including these elements in the modelling exercise would have meant making a series of necessary assumptions, and for this reason, a simple assumption (homogeneous probability of infection across herds) was considered the safest option. As the pool of positive herds is the outcome of a random sampling from the total number of herds, the sample will be representative of the area (i.e. more herds with small size). It could be argued that, as the prevalence is adjusted for small herds (see step 4), this means that the majority of the slaughtered animals would come from those small herds with a high prevalence, introducing an important bias (consider that positive herds with one animal have a within-herd prevalence of 100 %). In reality, this bias is mitigated by step 5 of the simulation model: as each animal in each herd has the same probability of being selected for slaughter, then the lower the number of animals in a herd, the less frequently this herd will be included in the calculation of the system sensitivity
4	Adjustment of the within-herd design prevalence as follows: • For herds with more than 1,000 animals: DP = 0.001 • For herds with fewer than 1,000 animals: DP = 1/herd size	This adjustment was included since for herds with less than 1000 animals the number of positive animals when the prevalence is 0.001 would have been less than 1, which is of course impossible. For those herds, an alternative design prevalence was calculated as 1 (the minimum number of positive animals) out of the total number of animals in that herd
5	Random selection from the positive herds of the proportion of animals to be sent to the slaughterhouse and tested	
6	Based on the adjusted design prevalence, calculation of the *HSe* for each herd (see Formula 1)	
7	Calculation of the *ASe* (confidence; see Formula 2)	

It has to be pointed out that the formula used in step 7 to calculate the *ASe* had to be adapted to the simulated scenario as follows:

$$SSe = 1 - \prod_{i=1}^{w}[1 - (HSe_i)] \quad 3$$

It can be seen that *BHPrev* no longer appears because the product includes only the *HSe* values from the ***w*** positive herds (which were selected randomly in step 3).

The simulation model was run under different scenarios (see Section 2.5.4).

2.5.3 Data input

In order to make the model work in a situation as close as possible to the actual scenario in Europe, it was decided to retrieve information from official European institutions and/or from official national institutions.

Data needed consisted of:

- the number of herds per country;
- the size of the herds and the number of herds of each particular herd size;
- the proportion of animals sent to the slaughterhouse per year per herd.

2.5.3.1 Number of herds per country

The data were retrieved from Eurostat, with experts' consent. The most recent information were for 2007 and came from 29 countries (27 MSS and two EAA countries; see Table 8).

Table 8: Summary statistics of the data on number of herds per country (source: Eurostat).

Minimum	First quartile	Median	Mean	Third quartile	Maximum	Records
230	18 630	40 840	113 100	104 900	1 068 000	29

It can be seen that the frequency distribution of the number of herds per country is skewed to the right: although the maximum number of herds is considerable (1,068,000), the median and the mean show much lower values (40,840 and 113,000 respectively), i.e. there are many countries with a low number of herds (Table 8).

As the interest was not on the specific situation of a given country, the data were used to make the evaluation in 29 different scenarios, with the purpose of reflecting the current European situation.

As the interest was not on the specific situation of a given country, the data were used to make the evaluation in 29 different scenarios, with the purpose of reflecting the current European situation.

2.5.3.2 Herd size

Three countries (Belgium, Denmark and the United Kingdom) provided EFSA with detailed official data on the number and size of herds from year 2011. The summary statistics are reported from Tables 9 to 11.

Table 9: Summary statistics on herd size data from Belgium (2011).

Minimum	First quartile	Median	Mean	Third quartile	Maximum	NAs
1	13	59	93.5	130	5 266	1

Table 10: Summary statistics on herd size data from Denmark (2011).

Minimum	First quartile	Median	Mean	Third quartile	Maximum
1	8	27	137.5	136	25 310

Table 11: Summary statistics on herd size data from United Kingdom (2011).

Minimum	First quartile	Median	Mean	Third quartile	Maximum
1	14	54	111.9	148	5 855

The descriptive statistics suggest that the distribution of this parameter is highly right skewed, meaning that the proportion of small herds is greater than the proportion of large herds.

Three different distributions were fitted to the data and the related Akaike information criterion (AIC) calculated. The results suggested that a Weibull probabilistic distribution does allow for a reduced loss of information.

The data from the three countries were then combined and analysed in the same way. Three probabilistic distributions were fitted and the AIC calculated. Again, the best-fitting probabilistic distribution was the Weibull, which was then adopted for the simulation modelling exercise.

2.5.4 Parameters and scenarios

2.5.4.1 Slaughter rate

The number of animals sent by each farm to the slaughterhouse is equal to the number of tested animals per farm, as all of them undergo the meat inspection.

The model was run under three plausible values for the replacement rate, i.e. the proportion of animals slaughtered per year per herd:

- 20 % (minimum)
- 35 % (best guess)
- 40 % (maximum)

The option of using a stochastic model was considered, but rejected. Although it is common to use a (Beta) Pert distribution in such a situation, this still represents a strong assumption. Indeed, the probability density between the best guess and the extreme values is arbitrarily imposed, while, in fact, no knowledge is available. If the true underlying distribution was bimodal, for example, the imposed Pert distribution would introduce an important bias which would be reflected in the final outcome. The option of comparing the outcome under three (in this case) scenarios as listed in the bullet points above (according to the so-called 'what if approach') was considered to be much safer than relying on an assumed probabilistic distribution, especially if exact information on the values between the extremes are not of interest.

2.5.4.2 Test (meat inspection) sensitivity

The problem of estimating the values to be used in the model for the Meat Inspection sensitivity (hereinafter referred to as 'test sensitivity') was approached in the same way as for the replacement rate (see Section 2.5.4.1).

In this case, it was decided to employ the sensitivity values derived from a meta-analysis by VLA (2011) (the detailed analysis of this information is published in a recent EFSA opinion (EFSA AHAW Panel, 2012b) for the current, classical, meat inspection (CL) (Table 12).

Table 12: Test sensitivity values (for classical meat inspection).

2.5^{th} percentile	Mean	97.5^{th} percentile
0.38	0.71	0.92

In addition to these values, it was agreed to use the lowest value available across the relevant scientific literature. This value comes from a study conducted in Ethiopia and is equal to 0.286.

The values to be used for the visual only option were estimated from the results of the COMISURV quantitative assessment (COMISURV report; Dupuy et al., 2012). In particular, two scenarios were explored, in which the visual only test sensitivity was threefold and fivefold lower than the current system (see Table 13).

Table 13: Visual only test sensitivity (for the Visual Only meat inspection option)

	Minimum	Mean	Maximum
Threefold lower	0.127	0.237	0.307
Fivefold lower	0.076	0.142	0.184

2.5.4.3 Within-herd prevalence (*WHP*) and herd prevalence (*HP*) in OTF countries

The design prevalence at the herd level (i.e. the threshold prevalence of positive herds or herd prevalence) was fixed at 0.1 % as described in the EU regulation for countries or part thereof that need to demonstrate freedom from bTB or keep the free status. The *WHP* was considered to be very low, i.e. the threshold prevalence of infected animals within a positive herd was assumed to be 0.1 % (i.e. equal to the *HP*). The values used for OTF countries can be seen as a 'worst case scenario' for a surveillance system as the two design prevalence values that have to be detected are extremely low. From an analytical point of view this is, actually, the best option as it evaluates the surveillance systems under investigation in an extreme and critical situation. This allows highlighting the potential weaknesses occurring when modifying the system, as in this case when the sensitivity at animal level is modified (i.e. lowered).

2.5.5 Results

The relevant prevalence values were set as follows:

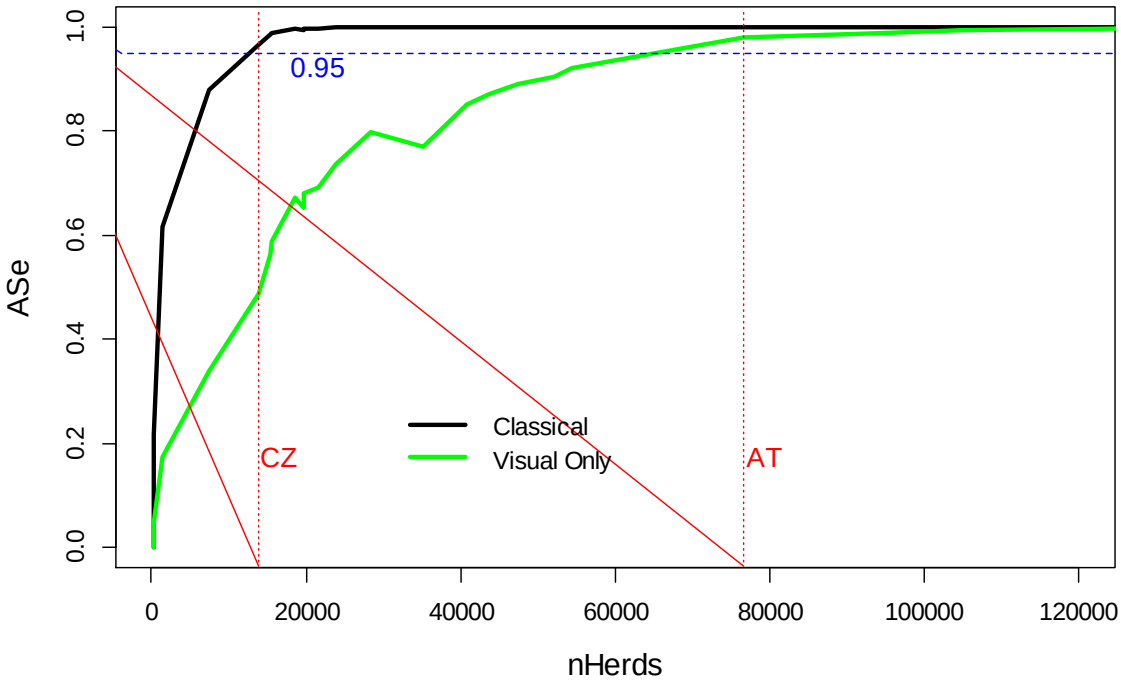
- *WHP*: 0.001 (for herds with more than 1000 animals) and 1/herd size (for herds with less than 1000 animals);
- *HP*: 0.001 (as prescribed in the legislation).

Note that the results presented in the main body of this report are the ones originated by a simulation based on the parameter values considered by the experts as the most likely, i.e.:

- a proportion of slaughtered animals per area (country or part of it) per year equal to 35 %;
- a classical test *Se* equal to 0.71, and
- a visual only test *Se* fivefold or threefold lower.

Additional results can be found in SAS technical report (EFSA, 2013).

Figure 2, in which the area sensitivity is a function of the total number of herds in that area, shows how the probability of detecting at least one positive farm, i.e. the detection ability of the system, decreases importantly when the visual only option is implemented.



Legend: *ASe* = area (country or part of it) sensitivity, i.e. probability of detecting at least one positive herd when the prevalence of positive herds is above 0.001, and nHerds = total number of herds in the area of interest.

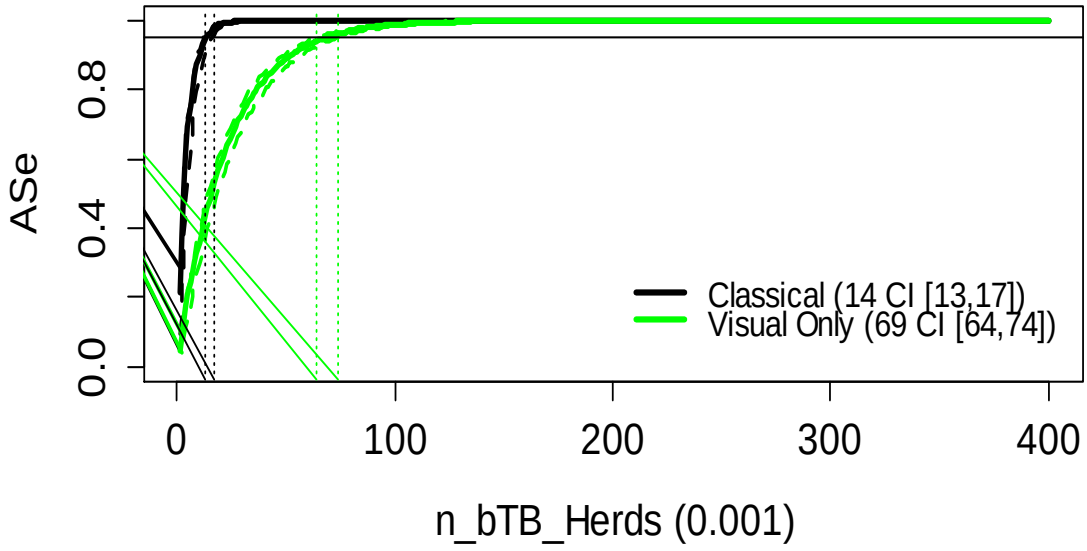
Figure 3: Probability of detection expressed in terms of area sensitivity as a function of the number of herds per area. The visual only test sensitivity is fivefold lower than the classical test sensitivity.

In other words, following a year when no slaughtered animal tested positive, under the present classical meat inspection system, 25 countries out of 29 would be 95 % confident that the prevalence of positive herds is below 0.1 %. In contrast, if implementing the visual only option, only 10 countries out of 29 would be able to reach the same conclusion with the same degree of confidence.

From a quantitative point of view, Table 14 shows that the *ASe* (i.e. the detection ability) for actual (classical) meat inspection reaches 95 % if the total number of herds is at least equal to 13,950. When implementing the visual only meat inspection option, the surveillance system needs at least a number of herds equal to 76,740.

Table 14: *ASe* calculated for 29 different situations in which the total number of herds increases. The 29 values correspond to data of 29 countries (source: Eurostat). Bold indicates *ASe* values above 95 %

COUNTRY	nHerds	ASeCL	ASe Visual only
MT	230	0	0
CY	290	0.217482	0.047721
LU	1 480	0.616178	0.173206
EE	7 420	0.878711	0.340372
CZ	13 950	**0.96537**	0.486835
SK	15 450	**0.985261**	0.563507
DK	15 590	**0.988591**	0.587077
FI	18 630	**0.996489**	0.672669
NO	19 640	**0.995201**	0.652827
HU	19 800	**0.99682**	0.680899
EL	21 540	**0.997342**	0.690684
SE	23 870	**0.998926**	0.738072
BE	28 470	**0.99968**	0.797255
NL	35 260	**0.999424**	0.769348
SI	40 840	**0.99994**	0.852985
CH	43 720	**0.999971**	0.871967
LV	47 350	**0.999987**	0.890855
PT	52 140	**0.999994**	0.905014
HR	54 370	**0.999997**	0.92021
AT	76 740	**1**	**0.981376**
UK	94 650	**1**	**0.988239**
IE	104 930	**1**	**0.995328**
ES	124 030	**1**	**0.997649**
LT	132 600	**1**	**0.998772**
BG	133 330	**1**	**0.998537**
IT	147 020	**1**	**0.999254**
FR	219 970	**1**	**0.999905**
PL	718 250	**1**	**1**
RO	1 067 730	**1**	**1**

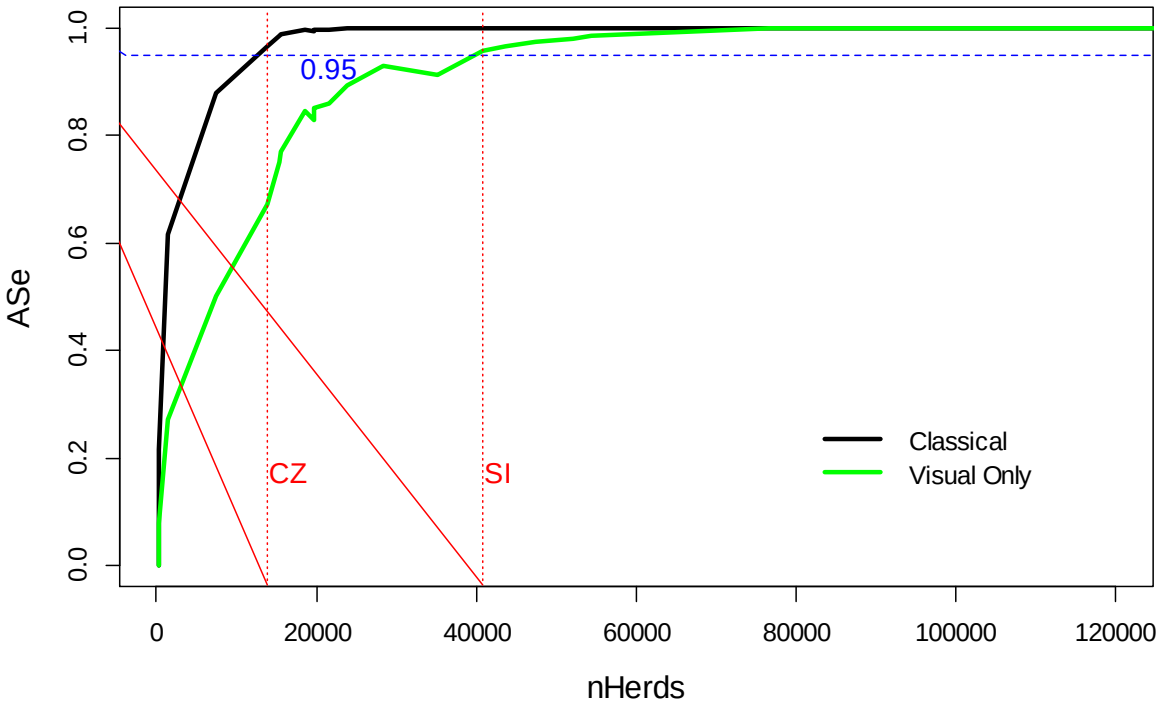


Legend: *ASe* = area (country or part of it) sensitivity, i.e. probability of detecting at least one positive herd when the prevalence of positive herds is above 0.001, and n_bTB_Herds = total number of positive herds in the area of interest (i.e. 0.1 % of the total herds).

Figure 4: Probability of detection expressed in terms of area sensitivity as a function of the number of bTB-positive herds per area. The visual only test sensitivity is fivefold lower than the classical test sensitivity.

The curves in Figure 2 are irregular as only 29 data points are available for estimation of *ASe*. In order to smooth the curves, the *ASe* values were displayed as a function of positive herds (rather than the total number of herds). A bit more in detail: an increasing number of herds were simulated; their size follows the fitted Weibull probability distribution used for the previous simulation. As only the herds with more than one positive animal contribute to the calculation, the attention can be focused on these ones only. The total number of herds can easily be calculated as the number of positive herds is just a proportion (i.e. 0.1 % of the total number of herds). Figure 3 provides a more detailed picture.

It can be seen that in order to be 95 % confident that the prevalence of positive herds is below 0.1 %, under the current meat inspection procedures, a median of 14 positive herds (CI [13–17]) need to be in the area (meaning that the total number of herds must be at least 14000, CI [13000, 17000]). In contrast, 69 positive herds are needed, under the visual only meat inspection, to reach the same conclusion with the same level of confidence, meaning that the total number of herds must be at least equal to 69000 (CI [64000, 74000]). From a more realistic point of view, it can be stated that, given the prevalence threshold set in the regulation and the number of animals sent to the slaughterhouse each year, an area with less than 64000 herds implementing the visual only option will never be able to be 95 % confident that the actual prevalence is below 0.001, even if all slaughtered animals tested negative. This number of herds in the area is much lower using the current meat inspection procedures: in this case, the areas that will not be able to reach a 95 % confidence will be those with less than 13000 herds.



Legend: *ASe* =area (country or part of it) sensitivity, i.e. probability of detecting at least one positive herd when the prevalence of positive herds is above 0.001, and nHerds = total number of herds in the area of interest.

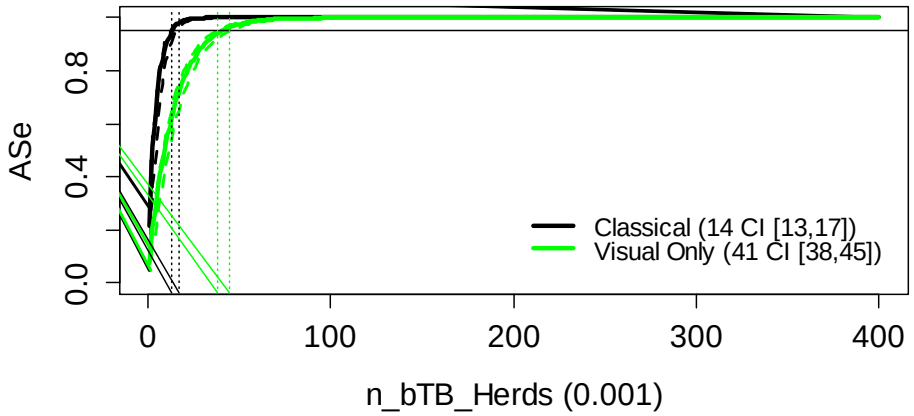
Figure 5: Probability of detection expressed in terms of area sensitivity as a function of the number of herds per area. The visual only test sensitivity is threefold lower than the classical test sensitivity

As expected, when the difference between the sensitivities of the two meat inspection options is smaller (that is, threefold lower, rather than fivefold lower), so is the difference in terms of ASe (see Figure 4). However, Table 15 shows that under current meat inspection conditions 25 countries would be able to detect at least one positive herd (when the prevalence of positive herds is above 0.1 %) with 95 % confidence, while, under visual only conditions, only 15 countries would be able to reach the same conclusion with the same degree of confidence.

Table 15: *ASe* calculated for 29 different situations where the total number of herds increases. The 29 values correspond to 29 countries (source: Eurostat). Bold indicates *ASe* values above 95 %. Visual only test *Se* = control test *Se*/3

COUNTRY	nHerds	ASeCL	ASe Visual Only
MT	230	0	0
CY	290	0.217482	0.07830184
LU	1480	0.6161783	0.27193147
EE	7420	0.8787106	0.50093838
CZ	13950	**0.9653698**	0.67156077
SK	15450	**0.9852608**	0.7497772
DK	15590	**0.9885914**	0.77164899
FI	18630	**0.9964885**	0.84509191
NO	19640	**0.9952007**	0.82896757
HU	19800	**0.9968203**	0.85131101
EL	21540	**0.9973416**	0.85900679
SE	23870	**0.9989259**	0.89353622
BE	28470	**0.9996795**	0.93027401
NL	35260	**0.9994244**	0.91382041
SI	40840	**0.9999401**	**0.95934352**
CH	43720	**0.9999711**	**0.96777097**
LV	47350	**0.9999869**	**0.97529122**
PT	52140	**0.9999938**	**0.98045438**
HR	54370	**0.9999972**	**0.98533042**
AT	76740	**1**	**0.99870971**
UK	94650	**1**	**0.9994006**
IE	104930	**1**	**0.99987191**
ES	124030	**1**	**0.999959**
LT	132600	**1**	**0.99998621**
BG	133330	**1**	**0.99998149**
IT	147020	**1**	**0.99999401**
FR	219970	**1**	**0.99999981**
PL	718250	**1**	**1**
RO	1067730	**1**	**1**

In addition, Figure 5 shows that in order to be 95 % confident of a prevalence of positive herds below 0.1 % under the current meat inspection procedures, a median of 14 positive herds (CI [13, 17]) need to be in the area (meaning that the total number of herds must be at least 14000, CI [13000, 14000]). Under the visual only meat inspection system, 41 positive herds would be needed to reach the same conclusion with the same level of confidence, meaning that the total number of herds must be at least equal to 41000 (CI [38000, 45000]). Again, from a more practical point of view, it can be stated that, given the prevalence threshold set in the regulation and the number of animals sent to the slaughterhouse each year, an area with less than 38000 herds implementing the visual only option will never be able to be 95 % confident that the actual prevalence of positive herds is below 0.001, even if all animals tested negative. This number of herds in the area is much lower if the current MI procedures are implemented: in this case, the areas that will not be able to reach a 95 % confidence will be those with less than 13000 herds.

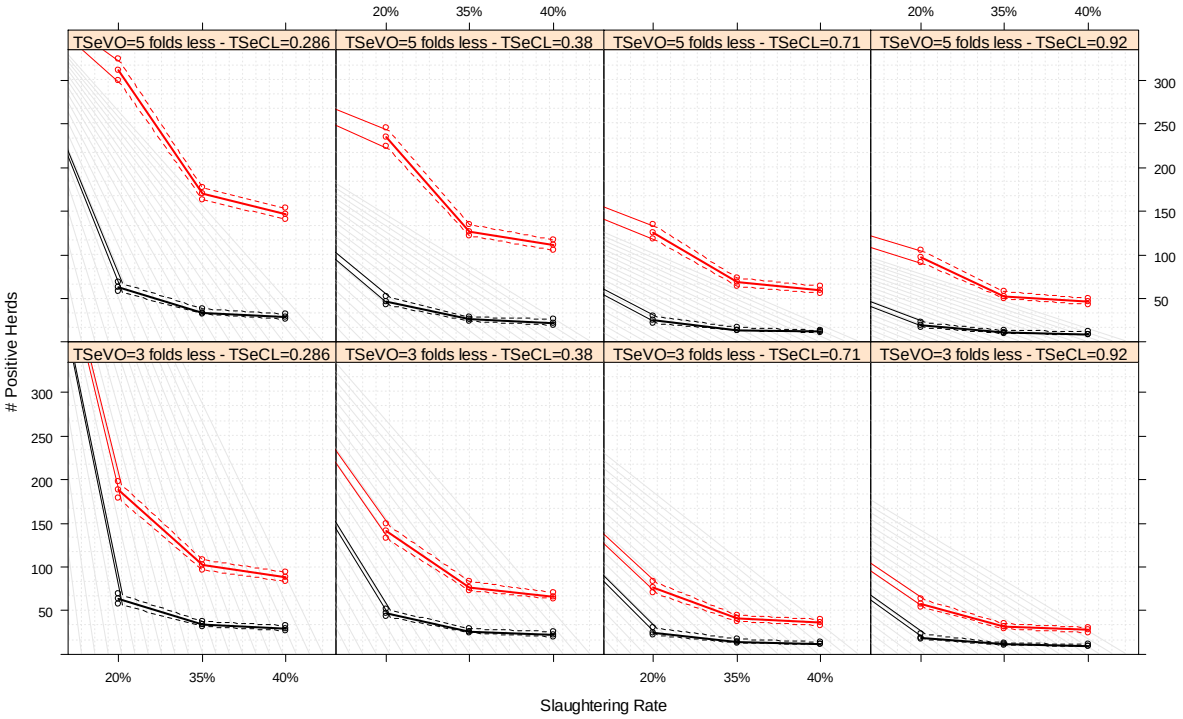


Legend: *ASe* = area (country or part of it) sensitivity, i.e. probability of detecting at least one positive herd when the prevalence of positive herds is above 0.001; n_bTB_Herds = total number of positive herds in the area of interest (i.e. 0.1 % of the total herds). Visual only test *Se* = classical test *Se*/3.

Figure 6: Probability of detection expressed in terms of area sensitivity as a function of the number of bTB positive herds per area. The visual only test sensitivity is threefold lower than the classical test sensitivity.

In order to be able to show all relevant information at a glance, the outputs of the simulations under the different scenarios are presented below in order to highlight the differences, in terms of test sensitivity, between the two meat inspection options.

Figure 6 shows how many positive herds are 'needed' (y-axis) in order to state, with 95 % confidence, that the area under investigation has a prevalence of positive herds below 0.1 %. Going from the left to the right, it can be seen that the number of positive herds that are needed (and therefore the total number of herds in that area) decreases as the sensitivity estimate of the current meat inspection (TSeCL) and the slaughtering rate increase. It is also clear that the smaller the difference in sensitivity between the current meat inspection and the visual-only option, the smaller the difference between the numbers of positive herds needed.



Legend: Solid black line = surveillance system (SS) based on current meat inspection. Black dashed lines = 95 % confidence interval. Solid red line = surveillance system (SS) based on visual-only meat inspection; Red dashed lines = 95 % confidence interval. Top row: TSeVO is fivefold lower than the TSeCL. Bottom row: TSeVO is threefold lower than the TseCL,

Figure 7: Minimum number of positive herds needed in order to reach a system (area) sensitivity of 95 % as a function of the slaughtering/replacement rate and of the sensitivity of the current meat inspection (TSeCL)

2.5.5.1 Probability of freedom (Pfree)

It must be noted that for this assessment the estimation of the probability of freedom (P_{free}), based on the Bayesian principles, was not estimated for two reasons:

- The EU OTF regulation only sets up the design prevalence at country (or part thereof) level and requests that the prevalence is below that threshold be substantiated on a yearly basis. In contrast, P_{free} is calculated across years, using a prior probability (system sensitivity of the previous year) to calculate the present (i.e. following a new year of testing) probability of being OTF, conditional on the result form previous year(s). Thus, this parameter does not fit the purpose of substantiating OTF status each year;

- Usually, this parameter is useful when the aim is to achieve a 'disease-free' status. As an example, a surveillance system with 95 % system sensitivity (if the probability of introduction is not particularly high) will be able to reach a 99 % probability of freedom in a few years. In this case, if the considered regions have already achieved OTF status, the aim is to keep it.

3. Implications for surveillance and monitoring for bovine health and welfare of changes to meat inspection as proposed by the CONTAM Panel

The conclusion and recommendations from the CONTAM Panel refer to areas such as the ranking system for chemical substances of potential concern; the use of FCI to help facilitate risk-based sampling strategies; and the inclusion of new hazards in control programmes for chemical residues and

contaminants (see CONTAM Appendix B, for full details). None of these were considered to have impact on animal health and welfare surveillance and monitoring.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- As shown by the COMISURV quantitative assessment, the change from the current meat inspection system to a visual only system would cause a significant reduction in the capability of detection (detection fraction) and/or probability of detection during meat inspection for granulomatous lesions (including bovine tuberculosis), *Taenia saginata* cysticercosis, fasciolosis (primarily for mild cases) and respiratory diseases. The magnitude of this reduction was assessed by expert opinion, due to the lack of empirical data on performance of a visual only meat inspection.

- The quantitative assessment by COMISURV showed that there is little difference in sensitivity between current and visual only meat inspection for any of the exotic diseases (malignant catarrhal fever, bluetongue, foot and mouth disease and vesicular stomatitis) considered.

- Detection of welfare conditions was not found to be affected, following the quantitative assessment by COMISURV, by the proposed changes to *post-mortem* inspection, as most of the conditions can be detected during effective ante-mortem inspection. However, at the moment, a list of animal based indicators of welfare, or guidance to their detection, is not available for scientific validation/review.

- It is shown by the COMISURV quantitative analysis that a shift to visual only meat inspection would have an impact on the overall surveillance (meat inspection and clinical surveillance) for fasciolosis and bovine tuberculosis.

- The role of slaughterhouse meat inspection in bovine tuberculosis surveillance is of great relevance for the surveillance of *Mycobacterium bovis* infection in herds and animals.

- During 2011, cases of bovine tuberculosis were found in cattle herds in 9 of the 12 non-OTF Member States. The proportion of existing positive herds within the non-OTF Member States increased slightly over the last five years, from 0.46 % in 2007 to 1.12 % in 2011.

- During 2011, a total of 194 cattle herds in OTF Member States were infected with *Mycobacterium bovis*, highlighting the need for continuous, effective bovine tuberculosis surveillance in these countries for continuing evidence of OTF status.

- In non-OTF Member States and zones thereof, surveillance of bovine tuberculosis is based on both on-farm testing and identification of new infected herds by current meat inspection at the slaughterhouse. Meat inspection makes a substantial contribution to the overall detection of new breakdowns.

- In OTF Member States and zones thereof, slaughterhouse meat inspection is the primary method of bovine tuberculosis surveillance, both for detection of residual *Mycobacterium bovis* infection, and for maintaining and substantiating infection prevalence below the limit established in EU legislation for granting and sustaining the OTF status.

- *Post-mortem* inspection is an important component of the overall bovine tuberculosis surveillance in both OTF and non-OTF Member States and zones thereof, and a reduction in the sensitivity of this component will substantially reduce surveillance quality. This effect may have the greatest impact in bovine tuberculosis surveillance in OTF Member States and zones thereof, which relies almost exclusively on surveillance by meat inspection.

- Estimates of the sensitivity of detection of bovine tuberculosis through meat inspection vary widely, reflecting different diagnostic methodologies and differences in inspection outcomes between slaughterhouses and inspectors.

- During detailed necropsy, incorporating both bacteriological culture and polymerase chain reaction, a sensitivity of 86.05 % has been achieved for the detection of tuberculous lesions in infected cattle. This sensitivity of necropsy as a diagnostic assay may be viewed as the upper detection limit of any practical slaughterhouse surveillance system for bovine tuberculosis.

- Current meat inspection procedures for tuberculosis detection have lower sensitivity than detailed necropsy (which includes dissection and slicing of lymph nodes, lungs, liver and spleen), being able to detect between 29.4 and 47 % of the infected animals detected by detailed necropsy.

- The determination of the true *Mycobacterium bovis* infection status of slaughtered skin test reactors is a crucial diagnostic step in the last stage of eradication of infection in herds. Mycobacterial isolation may be necessary to disclose *Mycobacterium bovis* infection for the correct classification of herds with skin test reactors. This implies the removal of lung samples and lymph nodes from these animals and their submission to the laboratory. These are important elements in the control of bovine tuberculosis in herds.

- The quantitative assessment by COMISURV to determine the contribution of meat inspection to animal health surveillance in bovine animals concluded that the change from the current meat inspection to a visual only system would cause a fivefold reduction in the effectiveness of detection of bovine tuberculosis, this effect being more prominent for early infection with small lesions.

- A qualitative risk assessment from the UK Food Standards Agency concluded that a change to a visual only inspection system would reduce the number of bovine tuberculosis cases found at the slaughterhouse using *post-mortem* inspection. The negative impact that this reduction would have on the overall surveillance and control of bovine tuberculosis was not quantitatively determined, but it was estimated to be greater in OTF Member States than in non-OTF Member States.

- Conclusions of recent assessments are consistent with previous EFSA opinions showing a negative impact on tuberculosis detection if palpation and incision of relevant organs (lung, respiratory tract lymph nodes) should be removed from inspection tasks.

- The quantitative model implemented to assess the impact of different meat inspection options on the overall sensitivity of a bovine tuberculosis surveillance system in OTF countries showed that a reduction in the sensitivity of bovine tuberculosis detection at individual (animal) level (due to the change to a visual only meat inspection) has a negative impact on the surveillance system sensitivity (i.e. the ability of the meat inspection surveillance system implemented in an area of interest to detect at least one positive herd when the prevalence is above the set threshold).

- The quantitative model showed that the difference in performance between the two meat inspection options (current or visual only) is mainly influenced by the slaughtering rate and the herd size, as these values determine the number of animals that are tested each year (*n*, the sample size). In fact, the smaller the proportion of animals sent to the slaughterhouse, the lower the overall sensitivity of the bovine tuberculosis surveillance system. This is why, when this proportion is low, only areas with a large number of herds will be able to reach the 95 % confidence.

- As the number of bovine herds in a given geographical area or country is a parameter not amenable to modification, this parameter becomes a limiting factor for the quality of the bTB surveillance. A reduction in meat inspection sensitivity arising from a change to a visual-only system would affect the area sensitivity in such a way that several EU Member States:

  - will not achieve a 95 % probability of detecting at least one positive herd when the true prevalence is above the threshold;

  - will be unable to state with 95 % confidence that the true prevalence of positive herds is below the threshold (i.e. 0.001) given that all slaughtered animals tested negative during meat inspection.

  This is because the number of herds in the country is lower than a required value estimated by the model, assuming slaughtering rates of between 20 % and 40 %.

- Prevalence of bovine cysticercosis in the EU, based on routine meat inspection slaughterhouse data, ranged from 0.01 to 6.8 %, with a great variation between MSs and zones. However, prevalence as measured by Antigen-capture-Enzyme-linked immunosorbent assays may be at least 10 times higher than that observed by meat inspection.

- Surveillance data for bovine cysticercosis are currently provided only through meat inspection at the slaughterhouse.

- Sensitivity of the current meat inspection for detection of bovine cysticercosis is considered to be low, and affected by the number of cysticerci harboured by infected animals, by the skill and awareness of meat inspectors, and by the quality of inspection.

- For bovine cysticercosis, taking detailed necropsy as a gold standard, routine meat inspection was able to detect between 17 % and 71 % of the animals classified as infected.

- The quantitative assessment carried out by COMISURV for this opinion found a significant decrease in effectiveness of detection of meat inspection when moving from the current to a visual only system for bovine cysticercosis, with a fourfold reduction in the detection fraction.

- The probable consequences of a further reduction in sensitivity if a visual only meat inspection were to be adopted would be an increase in the likelihood of transmission of *Taenia saginata* and, in turn, an increase in prevalence of the infection in bovine animals.

- Studies indicate that fasciolosis in cattle is underdiagnosed by clinical surveillance and that its prevalence, as determined by *post-mortem* meat inspection, can be high.

- The present *post-mortem* meat inspection procedure is the most effective tool in routine liver fluke surveillance in cattle, and a less sensitive, 'visual only' ,inspection of the liver would result in a reduction in the detection rate of liver fluke in individual bovine animals.

- Given the current prevalence of fasciolosis in cattle, it is unlikely that the reduction in animal-level sensitivity would significantly impact herd-level sensitivity (as it is unlikely that all infected cattle within a herd would be missed).

- The feedback to farmers about *Fasciola hepatica* detected at meat inspection is low at present.

- The consequences to animal health and welfare of a change to visual only meat inspection for the monitoring of fasciolosis were not considered to be significant.

- Regarding respiratory disease, cattle with lung pathology sufficient to reduce their performance may often go clinically undiagnosed and untreated.

- The palpation and incision of the lungs and related tissues, as defined by legislation, improves the sensitivity of detecting respiratory lesions.

- Prolonged travel distance and duration prior to slaughter are stressful to bovines and they do not recover fully irrespective of the resting period in lairage.

- Extended use of food chain information has the potential to compensate for some, but not all, of the information on animal health and welfare that would be lost if visual only *post-mortem* inspection is applied.

- Food chain information is a potentially effective tool to perform more targeted *ante-mortem* and *post-mortem* inspection tasks in the slaughterhouse which may increase the effectiveness of those tasks in detecting conditions of animal health and animal welfare significance.

- The existing ineffective flow of information from primary production to the slaughterhouses and vice versa reduces the ability to detect animal diseases and animal welfare conditions at the slaughterhouse and as a result limits possible improvements on animal health and welfare standards at the farm as farmers will not be aware of the slaughterhouse findings.

- None of the conclusions and recommendations on chemical hazards were considered to have an impact on animal health and welfare surveillance and monitoring.

RECOMMENDATIONS

- Animal based welfare indicators are available for on-farm welfare assessment of bovine animals, and these could be adapted to suit slaughterhouse conditions for effective *ante-mortem* detection of welfare conditions, including foot and leg disorders.

- Risk-based inspection procedures (including current or even more efficient *post-mortem* procedures) should be applied to skin test reactors to clarify the true *Mycobacterium bovis* infection status of the animal and of the herd. This is of greatest concern when bTB prevalence is low. Any change introduced in the current meat inspection should preserve this key element for bovine tuberculosis eradication.

- In order to avoid any reduction in the sensitivity of the overall surveillance system, meat inspection tasks aimed at detecting bovine tuberculosis as currently required by Regulation (EC) 854/2004 (palpation of the lungs and palpation and incision of retropharyngeal, tracheobronchial and mediastinal lymph nodes), should be retained.

- Current meat inspection is an important component of bovine tuberculosis surveillance, and the impact of any proposed changes in meat inspection protocols needs first to be assessed in the framework of the overall bovine tuberculosis surveillance strategy of the EU, to avoid a reduction in overall surveillance effectiveness. This is particularly important in OTF countries where field surveillance has ceased.

- If a visual only meat inspection system were to be adopted, alternative procedures should be applied that provide equivalent or even increased capability of detection than current meat inspection for bovine cysticercosis. At the meat inspection level there is preliminary evidence that masseter muscle incisions could be substituted by intensified inspection of the heart by practising additional incisions, compensating to a large extent for the loss in surveillance sensitivity.

- Lack of feedback of *post-mortem* results to the farmer prevents instigation of a liver fluke management programme, which could be detrimental to animal health and welfare. An improvement in this feedback of information is recommended as part of an effective meat inspection system.

- For respiratory diseases, an improved data collection and feedback system to primary producers is recommended.

- Animal based welfare indicators have been developed for the on-farm assessment of lameness in bovine animals (dairy cows) and could be adapted for use during routine *ante-mortem* inspection in slaughterhouses.

- Food chain information should include animal welfare status in order to complement the slaughterhouse surveillance systems (*ante-mortem* and *post-mortem* inspection) and the latter could be used to identify on-farm welfare status.

- An integrated system should be developed whereby food chain information for public health and for animal health and welfare can be used in parallel, more effectively.

- Provide farmers with background information on the animal diseases and welfare conditions of key concern that may affect their livestock and why it is important to provide this information to the slaughterhouse through the use of food chain information.

- The value of the Food chain information in guiding risk management to discriminate between animals subsequently going through different types of inspection procedures should be evaluated. Priority should be given to improving test sensitivity, noting that (pre-)screening tests should preferably produce few false negative classifications for the sake of animal disease detection and surveillance. Test specificity will largely be an economical parameter, since the subsequent inspection of all 'Food chain information –positive' animals or groups should detect any false positives not correctly identified during the Food chain information pre-screening.

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ANNEXES

Annex 1. Results from stage 2 models

Table A: Stratum-specific probabilities of detection for meat inspection when used to detect **respiratory diseases**; by AMI, PMI and AMI and PMI combined

Respiratory diseases		**AMI**		**PMI**						**Combined AMI and PMI**					
				Current			**Visual only**			**Current**			**Visual only**		
Prevalence of BVDV in area/age/case type	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**
High/young <6weeks/typical case	0.51	**0.59**	0.68	0.80	**0.87**	0.93	0.64	**0.76**	0.87	0.92	**0.95**	0.97	0.86	**0.90**	0.94
High/young <6weeks/mild case	0.08	**0.14**	0.20	0.50	**0.65**	0.79	0.31	**0.45**	0.58	0.61	**0.70**	0.79	0.45	**0.53**	0.61
High/young >6 weeks/typical case	0.45	**0.54**	0.63	0.81	**0.88**	0.94	0.58	**0.69**	0.79	0.92	**0.94**	0.97	0.82	**0.86**	0.90
High/young >6 weeks/mild case	0.05	**0.13**	0.21	0.55	**0.69**	0.82	0.36	**0.47**	0.58	0.64	**0.73**	0.81	0.46	**0.54**	0.61
High/adult/typical case	0.36	**0.46**	0.54	0.76	**0.84**	0.92	0.53	**0.65**	0.75	0.88	**0.91**	0.95	0.76	**0.81**	0.85
High/adult/mild case	0.03	**0.09**	0.16	0.49	**0.63**	0.76	0.31	**0.40**	0.50	0.57	**0.66**	0.75	0.39	**0.46**	0.53
Low/young <6weeks/typical case	0.48	**0.57**	0.66	0.80	**0.87**	0.93	0.63	**0.76**	0.87	0.92	**0.94**	0.96	0.85	**0.90**	0.93
Low/young <6weeks/mild case	0.08	**0.14**	0.20	0.47	**0.62**	0.77	0.31	**0.45**	0.58	0.58	**0.68**	0.77	0.44	**0.53**	0.61
Low/young >6 weeks/typical case	0.42	**0.52**	0.63	0.81	**0.88**	0.94	0.58	**0.69**	0.79	0.93	**0.96**	0.98	0.81	**0.85**	0.89
Low/young >6 weeks/mild case	0.05	**0.13**	0.21	0.54	**0.67**	0.81	0.36	**0.47**	0.58	0.56	**0.64**	0.71	0.46	**0.54**	0.61
Low/adult/typical case	0.35	**0.44**	0.53	0.76	**0.84**	0.92	0.53	**0.64**	0.75	0.88	**0.91**	0.94	0.75	**0.80**	0.85
Low/adult/mild case	0.03	**0.09**	0.16	0.48	**0.61**	0.74	0.31	**0.40**	0.50	0.56	**0.64**	0.73	0.39	**0.46**	0.52

Table B: Stratum-specific probabilities of detection for meat inspection when used to detect ***Cysticercus bovis***; by PMI and combined with AMI

Cysticercosis	**PMI**						**Combined AMI and PMI**					
	Current			**Visual only**			**Current**			**Visual only**		
Age/case type	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**
Young (over six weeks(/typical case	0.47	**0.59**	0.71	0.17	**0.24**	0.31	0.50	**0.58**	0.67	0.18	**0.24**	0.29
Young (over six weeks(/mild case	0.18	**0.29**	0.40	0.01	**0.05**	0.08	0.21	**0.29**	0.37	0.02	**0.05**	0.07
Adult/typical case	0.47	**0.59**	0.71	0.17	**0.23**	0.31	0.50	**0.59**	0.67	0.19	**0.24**	0.29
Adult/mild case	0.18	**0.29**	0.40	0.01	**0.05**	0.08	0.21	**0.29**	0.37	0.02	**0.05**	0.07

Table C: Stratum-specific probabilities of detection for meat inspection when used to detect ***Fasciola hepatica***; by PMI and combined with AMI

Fasciolosis	**PMI**						**Combined AMI and PMI**					
	Current			**Visual only**			**Current**			**Visual only**		
Prevalence in area/age/case type	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**
High/young (under six weeks)/typical case	0.43	**0.53**	0.62	0.33	**0.47**	0.59	0.46	**0.53**	0.60	0.38	**0.47**	0.56
High/young (under six weeks)//mild case	0.27	**0.36**	0.45	0.17	**0.26**	0.34	0.30	**0.36**	0.42	0.20	**0.26**	0.31
High/young (over six weeks)//typical case	0.67	**0.78**	0.88	0.48	**0.62**	0.75	0.71	**0.78**	0.85	0.52	**0.62**	0.72
High/young (over six weeks)//mild case	0.52	**0.64**	0.75	0.35	**0.44**	0.52	0.56	**0.64**	0.72	0.38	**0.44**	0.50
High/adult/typical case	0.67	**0.78**	0.88	0.48	**0.62**	0.75	0.71	**0.78**	0.85	0.52	**0.62**	0.72
High/adult/mild case	0.52	**0.64**	0.75	0.35	**0.44**	0.52	0.56	**0.64**	0.72	0.38	**0.44**	0.50
Low/young (under six weeks)//typical case	0.40	**0.51**	0.60	0.28	**0.41**	0.52	0.44	**0.51**	0.57	0.32	**0.41**	0.49
Low/young (under six weeks)/s/Mild case	0.21	**0.30**	0.39	0.09	**0.15**	0.20	0.23	**0.30**	0.37	0.11	**0.15**	0.19
Low/young (over six weeks)//Typical case	0.62	**0.74**	0.85	0.43	**0.56**	0.68	0.66	**0.74**	0.82	0.47	**0.56**	0.65
Low/young (over six weeks)//Mild case	0.45	**0.56**	0.67	0.28	**0.34**	0.41	0.48	**0.56**	0.64	0.30	**0.34**	0.39
Low/adult/typical case	0.62	**0.74**	0.85	0.43	**0.56**	0.68	0.66	**0.74**	0.82	0.47	**0.56**	0.65
Low/adult/mild case	0.45	**0.56**	0.67	0.28	**0.34**	0.41	0.48	**0.56**	0.64	0.30	**0.34**	0.39

Table D: Stratum-specific probabilities of detection for meat inspection when used to detect **granuloma** indicative of **bTB**; by PMI and combined with AMI

Granuloma/bTB	**PMI**						**Combined AMI and PMI**					
	Current			**Visual only**			**Current**			**Visual only**		
Prevalence in area/age/case type	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**	**5 %**	**Mode**	**95 %**
High/young (under six weeks)/typical case	0.69	**0.78**	0.87	0.12	**0.28**	0.43	0.72	**0.78**	0.84	0.17	**0.28**	0.39
High/young (under six weeks)//mild case	0.42	**0.55**	0.69	0.01	**0.08**	0.18	0.46	**0.55**	0.65	0.03	**0.08**	0.15
High/young (over six weeks)//typical case	0.73	**0.82**	0.91	0.12	**0.28**	0.43	0.76	**0.82**	0.89	0.17	**0.28**	0.39
High/young (over six weeks)//mild case	0.54	**0.66**	0.77	0.01	**0.08**	0.18	0.57	**0.66**	0.74	0.03	**0.08**	0.15
High/adult/typical case	0.73	**0.82**	0.91	0.12	**0.28**	0.43	0.76	**0.82**	0.88	0.17	**0.28**	0.39
High/adult/mild case	0.54	**0.65**	0.77	0.01	**0.08**	0.18	0.57	**0.66**	0.74	0.03	**0.08**	0.15
Low/young (under six weeks)//typical case	0.59	**0.70**	0.80	0.07	**0.22**	0.38	0.62	**0.70**	0.77	0.11	**0.22**	0.33
Low/young (under six weeks)/s/Mild case	0.35	**0.47**	0.59	0.02	**0.07**	0.13	0.38	**0.47**	0.56	0.03	**0.07**	0.11
Low/young (over six weeks)//Typical case	0.65	**0.76**	0.86	0.07	**0.22**	0.38	0.68	**0.76**	0.83	0.11	**0.22**	0.33
Low/young (over six weeks)//Mild case	0.36	**0.47**	0.58	0.02	**0.07**	0.13	0.39	**0.47**	0.55	0.03	**0.07**	0.11
Low/adult/typical case	0.65	**0.76**	0.86	0.07	**0.22**	0.38	0.68	**0.76**	0.83	0.11	**0.22**	0.33
Low/adult/mild case	0.36	**0.47**	0.58	0.02	**0.07**	0.13	0.39	**0.47**	0.55	0.03	**0.07**	0.11

GLOSSARY AND ABBREVIATIONS

AHAW	Animal Health and Welfare
AWO	Animal welfare officer
AMI	Ante-mortem inspection
BIOHAZ	Biological Hazards Panel
bTB	Bovine tuberculosis
CI	Confidence interval
CL	Classical (meat inspection)
CONTAM	Contaminants in the Food Chain Panel
CVO	Chief Veterinary Officer
DFD	Dark, Firm and Dry
EFSA	European Food Safety Authority
(Ag-)ELISA	(Antigen-capture) enzyme-linked immunosorbent assay
EU	European Union
FBO	Food business operator
FCI	Food chain information
FSA	Food Standards Agency
HACCP	Hazard Analysis and Critical Control Point
I	Incision
Non-OTF	Non-Officially Tuberculosis Free
MI	Meat inspection
MS	Member State
OIE	World Organization for Animal Health
OTF	Officially Tuberculosis Free
OV	Official veterinarian
P	Palpation
PCR	Polymerase chain reaction
PHR	Public health risk
PMI	Post-mortem inspection
V	Visual inspection
VO	Visual only (meat inspection)
WG	Working group

Case-finding capacity: characteristic of a surveillance system for endemic disease, describing the ability of the system to identify infected or affected herds or individuals, so that a control action can (potentially) be taken. The detection fraction is a measure of the case-finding capacity.

Case type: includes detectable (mild or typical cases) and non-detectable cases.

Clinical surveillance: surveillance based on clinical observations in the field.

Combined inspection: taking into account *ante-mortem* and *post-mortem* inspection.

Component sensitivity: the probability that one or more infected animals will be detected by the surveillance component during a specified time period, given that the disease is present at a level defined by the design prevalence.

Detectable cases: cases that are detectable by routine meat inspection procedures. They will express a range of combinations of clinical and pathological signs. A proportion of detectable cases will fit the definition of the typical case and a proportion will be milder cases.

Effectiveness of detection: the proportion of animals with lesions (i.e. detectable by visual inspection, palpation and/or incision) that are actually detected.

Detection fraction: the proportion of infected or affected units that are successfully detected by the surveillance system.

Early detection: investigating high risk samples with the aim of detecting disease or infection as quickly as possible after its introduction, i.e. faster than if a traditional sampling approach such as random sampling was applied.

Mild cases: the mild case of a disease or condition is the form that could be seen at the early stages of the disease or at some point between the subclinical and the fully developed (i.e. "typical") form. A mild case is neither typical nor subclinical. The animal will probably present more subtle signs than in a typical case. Mild cases fit the mild case definition validated by experts.

Monitoring: investigating samples or animals in order to obtain information about the frequency of disease or infection as it varies in time and/or space.

Non-detectable cases: cases that are beyond the detection capacity of current meat inspection protocols. These will often be early cases at a stage where distinct clinical signs have not yet developed, but they can be cases with mild infection that leads to only subclinical conditions, without pathological lesions detectable by meat inspection.

Non-overlapping probability intervals: indicates that scenarios differ significantly from each other.

Overall surveillance (system): includes several components, such as slaughterhouse surveillance and clinical surveillance.

Slaughterhouse surveillance (system): surveillance by meat inspection in slaughterhouses.

Stage 2: assessment of the probability of detection at meat inspection. The objective of Stage 2 modelling was to estimate case type-specific (for typical and mild cases) as well as overall probabilities of detection at meat inspection.

Stage 3: assessment of the relative effectiveness of meat inspection within the overall surveillance system by comparing meat inspection with other available surveillance methods.

Typical cases: cases that are, by definition, detectable cases and express more developed clinical signs than mild cases. They fit the typical case definition provided by the experts, which is defined as signs and/or lesions that are expected to be observed in more than 60 % of affected or infected of animals seen at the slaughterhouse.